restrict agencies' ability to manage care efficiently.

Comment: One commenter was concerned about the high relative payment weight associated with therapy-threshold case-mix groups, and because of this concern, questioned whether the Abt Associates sample was representative of agencies in the industry offering therapy programs.

Response: The Abt Associates sample used to develop the case-mix groups was selected to be representative of national service delivery patterns. The 90 participating agencies were selected from all four census regions of the country, from among different ownership categories (freestanding for-profit, freestanding voluntary/private nonprofit; hospital-based; and government), from both urban and rural areas, and from among agencies with high, medium, or low practice patterns (as measured by the number of visits per-episode in 1995). As we note elsewhere in this rule, in our subsequent analysis of OASIS data and utilization data for the nation as a whole, we have found that these agencies on average appear to resemble the nation closely. We have no reason to believe that their therapy service delivery is unusual and would result in an inaccurate relative weight for therapy-threshold cases.

Wound Care Patients

Comment: Many commenters argued that services for many wound patients would be inadequately reimbursed under the proposed case-mix system. One often cited reason was the high cost of wound supplies for some patients. Some commenters recommended that wound supplies costs should be directly reimbursed, rather than being bundled into the episode payment.

Response: We have not adopted this recommendation. We have no statutory authority to unbundle the wound supplies costs. All supplies costs are now in the base costs used in determining the payment amount. As we note in our response to comments on omission of time spent outside the home from the calculation of resource costs, the current system of relative weights assumes that the omitted costs are directly proportional to time spent in the home. We will consider methods for testing this assumption, including the impact on wound care reimbursement. Case-mix model revisions, adopted in response to comments concerning wound care patients, have resulted in increased payments for wound care patients. These are described below and in the section on changes to the case-mix model.

Comment: Several commenters noted that the clinical dimension does not address wounds from trauma.

Response: In response to this comment, we have added a variable to identify trauma and burn patients who have wounds. This variable is now included in the clinical dimension. If a patient has a primary diagnosis of trauma or burns and OASIS item M0440 indicates that there is a wound, the clinical score is increased by 21 points.

Comment: A commenter recommended that the scoring for pressure ulcers in the clinical dimension should take into account their number, size, condition, or complexity.

Response: The clinical dimension in the proposed rule took into account the stage of the most problematic observable pressure ulcer, if any. OASIS does not record the size of pressure ulcers. The assessment covers the number of pressure ulcers at each stage. The status of the most problematic observable pressure ulcer is also reported. These stage and status measures are intended to measure the condition and complexity of the pressure ulcers.

In accordance with the comments on pressure ulcers, we re-examined the impact of the pressure ulcer stage and status variables, and the number of pressure ulcers by stage, in the Abt data. We analyzed a newly available larger learning sample of 11,503 episodes. As a result of these analyses, we identified a statistically significant score to add to the clinical dimension score if the number of pressure ulcers at stage three or four is two or more. This variable is now included in addition to the original variable measuring the stage of the most problematic pressure ulcer. It adds 17 points to the clinical score. As in our earlier investigations, the status of the most problematic observable pressure ulcer did not contribute significantly to the model after the other variables were included. As we continue to study revisions to OASIS, we will consider including additional data on such factors as the size of pressure ulcers.

Comment: Several commenters indicated that wound variables should be more detailed to provide better reimbursement for wound patients who score low on the clinical dimension but nevertheless incur high costs. For example, a commenter stated that if a stasis ulcer status is early/partial granulation, no points are given, but this does not make sense if the goal is to heal the wound. Another commenter recommended that early/partially granulating stasis ulcers should be given 24 points to make the case-mix system's treatment of stasis ulcers consistent with its treatment of surgical wounds.

Response: In addition to analyses on pressure ulcers (described above), we re-examined the definition of the case-mix variables for the status of stasis ulcers and surgical wounds. We used the newly available larger learning sample of 11,503 episodes. As a result, we have identified separate score values to add to the clinical dimension for early/partial granulation. These scores are 14 and 7 for the early/partially granulating most problematic stasis ulcer and early/partially granulating most problematic surgical wound, respectively. Revised scores for the most problematic nonhealing stasis ulcer and most problematic nonhealing surgical wound are 22 and 15, respectively.

In further attempts to more accurately measure the severity of wound patients, we investigated interactions between wound severity and several comorbidities (for example, diabetes) and immobility, but statistical results generally did not support including such interactions as additional score-bearing variables. In future work refining the case-mix model, we plan to use national claims and OASIS data to continue investigating comorbidities. Agencies could assist such efforts by reporting diagnosis codes on OASIS at the complete four-digit or five-digit level, as recommended by the official coding guidelines.

Comment: One commenter reasoned that costly wound patients, especially severe pressure ulcer patients, often may receive additional points in the clinical dimension for other problems (for example, diabetes or vision problems), but there is no recognition in the case-mix system for a sum of clinical points exceeding 27. In a similar vein, another commenter recommended creating a fifth severity level in the clinical dimension to increase payments for severe wound patients.

Response: In addition to refining measures for pressure ulcers, stasis ulcers, and surgical wounds, in a further effort to improve payment accuracy for wound patients, we have revised the case-mix system by re-defining the clinical severity score intervals. The revised score intervals are as follows: minimal severity: 0–7; low severity: 8–19; moderate severity: 20–40; high severity: 41+. The relative frequencies in the Abt sample for the revised clinical severity levels are 30 percent, 36 percent, 28 percent, and 6 percent, for minimal, low, moderate, and high clinical severity, respectively. (In the proposed rule, the corresponding percentages were 30 percent, 30 percent, 23 percent, 17 percent) This change has

generally resulted in higher case-mix relative weights for the case-mix groups involving moderate and high clinical severity. It has also resulted in a wider range of weights for therapy-threshold case-mix groups and non-therapy-threshold case-mix groups. We have not added a fifth level of clinical severity. Given the array of the clinical scores in the sample, the amount of sample data available, and our objective of administrative feasibility, at this time we believe that four clinical severity levels is an appropriate structure for the case-mix model.

Comment: In commenting on the status of wound care patients under the case-mix system, several commenters specifically stated that services for daily care wound patients would be inadequately reimbursed under the proposed rule. Some commenters recommended that we add a variable to the services utilization dimension that recognizes skilled nursing hours, analogous to our use of therapy hours in the services utilization score. They suggested that this would be a way to remedy inadequate payment for daily wound care patients while recognizing the skilled wound treatments that contribute to their higher costs.

Response: The wound care patient must be deemed eligible for the Medicare Home Health Benefit which dictates that the skilled nursing care be provided on an ''intermittent'' basis, as required by sections 1814(a)(2)(C) and 1835(a)(2)(A). The ''intermittent'' skilled care provided must be either provided or needed on fewer than 7 days each week or less than 8 hours of each day for periods of 21 days or less (with extensions in exceptional circumstances when the need for additional care is finite and predictable). The need for skilled nursing care for a wound care patient on a continuing basis is contingent upon evidence documented in the patient's record that the wound is improving in response to the wound care provided. It is neither reasonable nor medically necessary to continue a given type of wound care if evidence of wound improvement cannot be shown.

For the following reasons, we are not accepting the recommendation that skilled nursing hours be treated comparably with therapy hours in order to address the needs of costly wound care patients. First, as described previously concerning changes to the case-mix system, we have made additions and modifications to the clinical dimension in an attempt to better capture variations in clinical severity associated with wound care patients. Second, we are concerned that adopting an additional utilization-based measure strongly compromises the intention of home health payment reform to move away from a cost-based system. Finally, we are also concerned that in some instances extended wound care episodes may reflect inattention to the statutory eligibility requirement regarding ''finite and predictable'' need, and to our policy that continuing wound care must be efficacious. We will, however, continue reviewing the OASIS wound measures and the case-mix system's ability to adequately reflect the needs of wound care patients.

Daily Insulin Injection Patients

Comment: Many commenters identified diabetic patients requiring daily insulin injection as a group similar to daily wound care patients in terms of their extraordinary costs. They maintained that such patients might experience access barriers because the case-mix system does not account for their extraordinary care needs. They further indicated that the proposed outlier payment methodology would not necessarily result in payments adequate to compensate agencies for the cost of these patients.

Response: The OASIS does not provide information allowing accurate identification of these diabetic patients. Daily insulin patients appear to be a heterogeneous group, some of whom can be taught self-injection. There are no variables on the OASIS assessment that clearly distinguish such patients from others unable or unwilling to self-inject. As the outlier payment is intended to compensate for difficulties in case-mix measures, we have determined that daily insulin injection patients are likely candidates for outlier payments. We assume that daily injection visits tend to be low-cost visits, so it is likely that outlier payments will be adequate for many daily insulin patients.

Diagnoses Included and Excluded From the Clinical Dimension

Comment: The case-mix system discussed in the proposed rule recognized three diagnostic categories in the clinical dimension. These were certain orthopedic and neurological diagnoses, and diabetes. Diagnoses in these groups are assigned a score to help determine the patient's clinical dimension total score when the diagnoses appear in the OASIS primary home care diagnosis field (M0230A). A commenter suggested that we classify all diagnoses. Other commenters stated that the three categories proposed do not include all high-acuity diagnoses.

Response: From our work with the Abt Associates sample, we concluded that a complete classification of all diagnoses would not necessarily make the case-mix system appreciably more accurate, but it would make the grouping system more complex. In developing the clinical dimension, we studied the effect of placing every patient in one of several defined groups of diagnoses (such as orthopedic, cardiovascular/pulmonary, psychiatric). We investigated how this classification contributed to explaining resource use in home care. The three groups in the proposed rule stood out as accounting for significantly higher costs on average than other groups we defined. Adding the other groups to the model did not appreciably raise the explanatory power of the case-mix adjuster. Consequently, we believe that restricting recognition in the clinical dimension to the orthopedic, neurological, and diabetes groups balances our payment policy objectives of payment accuracy and administrative feasibility. We have not added any diagnoses to these three groups published in the proposed rule. However, we have added a variable to identify certain wound patients. This variable uses selected diagnoses codes from the primary diagnosis (OASIS item M0230, line a). We added this new variable to respond to comments we received about wound patients.

We are continuing to study a variation of the case-mix system that recognizes more diagnostic groups, but it would be a more complicated system with a substantially larger number of groups. We would require any such system to explain significantly more variation in resource cost than does the current model, in order to justify the added administrative complexity.

Currently, the OASIS instructions do not require complete four-digit and five-digit coding of the primary and secondary home care diagnoses. Three-digit coding of the category code is allowed, although agencies may voluntarily report complete four and five-digit coding. In the interests of future case-mix refinement, we will consider requiring that all agencies report the complete code. Such a requirement would conform OASIS with existing coding guidelines in the Medicare program and nationally.

Comment: One commenter pointed out that we did not list all diagnoses in the three groups in the clinical dimension, and requested confirmation that this was an error.

Response: The list of code categories presented in the proposed rule was complete. We omitted certain code categories based on clinical judgment and knowledge of coding practices in the community. We believe that

including these codes would reduce the explanatory power of the model, because they are likely to consist of heterogeneous or low-cost cases. When we examined the resource cost of orthopedic diagnoses omitted from the orthopedic group, we found indications that confirmed our decision.

Comment: Several commenters indicated that they believed the list should not exclude common diagnoses.

Response: Some of the diagnoses cited by commenters are frequently encountered in home care. It was not our objective to identify common diagnoses, but to pinpoint conditions that were associated with variations in resource cost. Some common diagnoses are associated with widely varying needs for home care services, which would tend to make them poor predictors statistically.

Comment: Some commenters suggested that the case-mix system recognize certain diagnoses in addition to those listed. Several commenters mentioned cardiac, respiratory, cardiopulmonary, and ''other circulatory'' diagnoses.

Response: As noted previously, cardiac, vascular, and respiratory diagnoses were a category studied during development of the clinical dimension, but the category did not demonstrate a contribution to the model sufficient to justify its inclusion, after we accounted for existing elements such as dyspnea and wound problems. We will continue to study this group of diagnoses.

Comment: We received various comments suggesting that we should have included psychiatric, mental health, or behavioral diagnoses. A commenter stated that three points for mental health conditions is inadequate, citing the additional credentials Medicare requires for psychiatric nurses as a reason for higher costs of psychiatric patients. Another commenter noted that depression, common among many elderly patients with health problems, negatively affects response to treatment. One commenter suggested the addition of ''780 (alteration of consciousness)'', in order to ensure access for psychiatric patients.

Response: In the clinical dimension, we included MO610 on behavioral problems to capture both cognitive and behavioral factors affecting resource cost. If the assessing clinician checks one or more of the response categories, three points are added to the clinical dimension. During case-mix system development, we examined diagnoses and various OASIS assessment items relating to mental health, sensory, and cognitive status. Specific to mental health, we looked at the relationship between home health resource use and mental health diagnoses (psychoses, drug psychoses, and neurotic disorders). We found that this group of conditions did not greatly contribute to explaining variation in resource use in home care after including functional, clinical, and service factors in the case-mix model.

However, we do *not* interpret our statistical results as necessarily indicating that mental health issues are unimportant in home care. One reason our statistical findings do not support including further information specific to mental health status is that the remaining functional and service factors in the case-mix system already capture the costliness of these patients. Thus, the impact of behavioral health issues is being recognized in factors other than diagnosis-specific elements. Other possible reasons for our statistical findings may stem from the extreme impairment of many psychiatric patients, which can lead to periods of institutional care and extensive informal support in the home. Such factors may tend to reduce the measured resource cost.

In future review of the case-mix system, we will continue to study case-mix measures for mental health patients.

Comment: A few commenters suggested that we include cancer diagnoses in the list of diagnoses for clinical dimension scoring.

Response: Several cancer diagnosis code categories appear in the orthopedic and neurological lists used in the case-mix model. We found no evidence during case-mix development activities that cancer diagnoses should be a separate group in the clinical dimension. We believe that part of the reason is that care needs for certain cancer patients (for example, functional assistance, wound care, pain management) are already accounted for in the case-mix model. Therefore, we have not added any more cancer diagnoses to the final regulation.

Comment: A commenter suggested that we include terminal cancer patients as a diagnosis group. Another commenter stated that end-stage cardiac/respiratory disease cases should be included.

Response: We have not added terminal cancer patients or end-stage cardiac/respiratory cases as a special diagnostic category. There are no OASIS items directly identifying these cases. In developing the case-mix model, we considered including OASIS items assessing overall prognosis and life expectancy, which potentially have a use in identifying terminal cancer patients. However, we concluded that these items are inappropriate elements for payment policy because of their inherent subjectivity and vulnerability to gaming. Moreover, statistical analyses have suggested the life expectancy item has poor scientific reliability.

Comment: A commenter suggested that we add category code 438, ''late effects of cerebrovascular disease'', to the list of neurological diagnostic categories because it is extremely common in home care and is the correct code assignment following hospitalization for an acute cerebrovascular accident (codes 434 and 436). The commenter added that we should delete codes 434 and 436 because coding guidelines reserve them for hospital coding.

Response: We have not adopted this suggestion. Codes 434 and 436 are being used in home care, notwithstanding the coding guidelines. In the Abt case-mix data, episodes coded with 436 are about nine times as common as episodes coded with 438. Code 434 is also used, but appears only about one-third as often as 438. The definition of 438 encompasses sequelae whose lags may be of any length. For this reason, we believe that including 438 presents significant risks of inappropriate payment. We will continue to examine the applicability of code 438 in future work.

Comment: A few commenters suggested that we include joint replacement diagnoses in the orthopedic diagnosis group.

Response: Joint replacement diagnoses are V-codes, which are not used on the OASIS assessment. Therefore, we did not study or specify including such codes in the case-mix system. However, care needs of many joint replacement patients are addressed in the therapy-threshold variable of the services utilization dimension and in the functional dimension. In setting the therapy threshold, based primarily on clinical judgment, we had in mind the treatment needs of the many joint replacement patients covered by the Medicare home health benefit.

Comment: Several commenters requested clarification about the omission of certain orthopedic diagnosis codes from the orthopedic group. These comprised 715 (osteoarthrosis and allied disorders), 719 (other and unspecified disorders of joint), 726 (peripheral enthesopathies and allied syndromes), 727 (other disorders of synovium, tendon and bursa), and 729 (other disorders of soft tissues).

Response: The exclusion of these diagnoses was intentional, based on clinical judgment that they are often

reflective of low case severity, and therefore unsuitable for the purposes of the groups defined in the proposed rule. Statistical information supports this judgment. In the Abt data, the average resource cost of the omitted diagnoses was 85 percent of the average resource cost of the included diagnoses, an indication that the excluded codes' cost impact is significantly lower. We also found statistical evidence that including these code categories in the current orthopedic diagnosis group does not improve, and may slightly reduce, the predictive value of the diagnosis groups included in the clinical dimension.

Comment: A commenter recommended that we add category code 733, ''other disorders of bone and cartilage'', to the orthopedic group because this category includes pathological fractures. The commenter added that requiring greater specificity in code assignment, beyond the three-digit category code, would allow inclusion of the pathological fracture codes without inclusion of other diagnoses in category 733.

Response: We disagree. We did not add 733 because the range of severity in this category may be very wide. For example, this code category includes osteoporosis, a very common condition in the elderly population. On the other hand, 733 also contains aseptic necrosis of bones, and aseptic necrosis of the femoral head is an indication for hip joint replacement. Without more information about the specific frequency of diagnoses, we expect that the osteoporosis cases would be much more common. We believe that adding this category code to the orthopedic group increases the risks of inappropriate payment. We will continue to study the excluded diagnosis codes. We agree that greater specificity in coding could solve this problem. Agencies can assist our efforts to develop information about the usefulness of specific codes in case-mix models by reporting diagnoses at the complete four-digit and five-digit code level.

Comment: One commenter suggested that we add diagnosis code category 707 (chronic ulcers) to the orthopedic category because these patients may present high costs for such services as debridement and dressing changes.

Response: The orthopedic group is not an appropriate placement for this code. However, as noted elsewhere in this rule, we have added assessment items to the clinical dimension in an attempt to strengthen the case-mix measurement for wound patients.

Comment: A commenter stated that we should include the diagnosis severity index on OASIS in the clinical dimension scoring.

Response: We did not include this assessment item because we believe its inherent subjectivity and vulnerability to gaming make it unsuitable for use in the case-mix model. Preliminary statistical analysis suggests the scientific reliability of the index is low for orthopedic and neurological diagnoses.

Comment: One commenter stated that the categories included in the diagnosis groups were unrealistic and unrelated to the need for home care services in an elderly population.

Response: Our statistical information indicates otherwise. The statistical results are shown in Abt Associates, Second Interim Report, September 24, 1999, Appendix H. They indicate that the incremental cost associated with each of the diagnosis groups is large and highly statistically significant.

Comment: We received various general and specific comments suggesting the use of secondary or multiple diagnoses in the clinical dimension. Some commenters stated that comorbidities are important in determining patient needs, and therefore they should be recognized in the case-mix system. A commenter suggested that, to improve the accuracy of the clinical dimension score, patients with multiple diagnoses from the existing groups should be credited with additional points in their clinical dimension measurement. One commenter suggested considering the first three diagnoses in order of importance. A couple of commenters mentioned diabetes as a secondary diagnosis that may appear in conjunction with wound care as a primary diagnosis, a situation that, if accounted for in scoring, might improve payment accuracy.

Response: Although we agree that multiple diagnoses and comorbidities warrant consideration, we have not used any of these suggestions because data and time constraints do not allow adequate evaluation of their contribution and impact on resource cost. To conduct an orderly exploration of the impact on case-mix measurement, and to assign a valid score in such cases, would require more observations than the Abt data set contains. We did test the impact of diabetes on severe wound patients, but the results suggested that some of the most severe wound patients would be paid inappropriately if the clinical score was increased. Further analysis of these suggestions to fully understand the implications can be undertaken with appropriate resources. We intend to use national claims data linked to OASIS to investigate multiple diagnoses/comorbidity issues in future case-mix analyses. We believe that such an effort would be significantly aided by complete four-digit and five-digit diagnosis coding on the OASIS record.

Comment: Commenters suggested that we credit the points published in the proposed rule for the neurological, orthopedic, or diabetes groups to the patient's clinical dimension score whether the diagnosis is primary or secondary.

Response: We believe such suggestions should be tested empirically to derive an appropriate score as there is more than one way to implement this suggestion. These are subjects for study when larger data resources become available.

Comment: Two commenters stated that the adjuster's use of a limited number of diagnosis groups will lead to more coding of the specified diagnoses as the primary diagnosis, distorting national data that would be used to make refinements of the system.

Response: We believe such practices would be counterproductive. Payment-motivated coding can eventually lower the predictive ability of a case-mix measure, and result in less differentiation among case-mix groups. We will continue to examine the accuracy of the case-mix model and the reliability of the data used for determining payments. If necessary, we would adjust the case-mix weights in response to those studies. As stated in the proposed rule, we intend to revise the case-mix weights over time to adjust for changes in patient population, actual changes in home health care practice patterns, and changes in the coding or classification of patients that do not reflect real changes in case-mix.

Comment: A commenter expressed concern that the quality of the diagnosis codes reported for home care are of such poor quality that they would be of no value in the development of the prospective payment system.

Response: We recognize the commenter's position, but we believe diagnoses are still useful in developing a case-mix model. The three diagnosis code categories in the model are the strongest contributors of all the diagnosis groups we defined in conducting our analyses on the Abt sample. We will continue to study the usefulness of diagnoses, and believe that agencies can assist our efforts by reporting diagnoses at the complete four-digit and five-digit code level.

Comment: One commenter urged us to clearly define ''primary home care diagnosis'' to prevent inappropriate upcoding.

Response: The OASIS implementation manual suggests strategies for the assessor to use in identifying the diagnoses for the diagnosis reporting items (M0230 and M0240). There is no specific guidance on differentiating the primary from secondary diagnoses. However, a definition for the primary diagnosis on the physician certification and plan of care (HCFA form 485) is discussed in the Medicare Home Health Agency Manual. We believe agencies are very familiar with the instructions in the Manual. The diagnosis guidance in the Manual is consistent with the language used in the OASIS instructions. (One difference, however, is that the Manual allows V-codes and the OASIS does not.) Nonetheless, we agree that it might be desirable to expand the instructions on the OASIS in the future. We will consider this in modifications to the OASIS form.

Comment: One commenter stated that the OASIS diagnosis reporting requirement that allows only three-digit ICD–9–CM category codes to be reported has a severe adverse impact on clinical severity data and, thus, adversely impacts the design of the home health classification system. The commenter noted that this practice violates official coding guidelines.

Response: We agree that a lack of specificity in code assignment somewhat diminishes accurate case-mix development and ascertainment. To help rectify the situation, we urge agencies to voluntarily code to the complete four-digit or five-digit code level.

Comment: A commenter expressed concern that the OASIS reporting requirements do not allow V-codes, in contrast to official coding guidelines approved by HCFA which accept V-codes as potentially the most appropriate codes in some circumstances in the home health setting. The commenter cited the distinction between acute fracture codes in the hospital setting and aftercare codes in the home health setting. According to the commenter, this conflict with the official coding guidelines threatens the consistency and uniformity of national health care data, resulting in data that are of poor quality and little value.

Response: The OASIS instructions state that instead of V-codes the agency should list the relevant diagnosis. This requirement was installed to serve the needs of OASIS as it was originally designed—as a quality assurance tool. We have adopted OASIS as a valuable quality assurance tool. Therefore, any changes in coding policy on OASIS would have to balance the quality assurance objectives with the consistency and uniformity objectives articulated by the commenter. At this time we do not believe that adopting V-codes is consistent with the needs of either OASIS or the case-mix system. Regarding case-mix, one of our objectives is to classify patients with minimal reliance on treatments planned or received. Given that objective, there is little clear benefit from adopting the applicable V-codes intended to indicate aftercare services.

Comment: A commenter stated that certain category codes in the three diagnosis groups to be identified from the OASIS primary diagnosis field (M0230) should never be reported as primary diagnoses, according to ICD–9–CM coding rules and official coding guidelines. These diagnoses must be used with a higher-coded diagnosis that indicates the etiology. The affected ICD–9–CM category codes are 711, 712, 713, 720, 730, 731, 320, 321, 323, 330, 331, 334, 336, 337, 357, and 358.

Response: In accordance with this comment, we have listed the affected codes (not code categories) in Table 8 as either primary or secondary diagnoses at the applicable four- or five-digit level. We will recognize these diagnosis codes in the case-mix adjuster only if the following conditions are met: (1) Manifestation codes (that is, codes that can never be used as the primary diagnosis) must appear as the first secondary diagnosis (line b, under ''other diagnoses'' in OASIS M0240) and must appear with all digits required by ICD–9–CM coding rules. (2) Remaining codes from the affected categories must appear as the primary diagnosis (line a, under OASIS M0230) and must appear with all digits required by ICD–9–CM coding rules. The requirement to report manifestation codes as the first secondary diagnosis is consistent with our intention to recognize the primary diagnosis for case-mix purposes. In this circumstance, the primary diagnosis is indicated by the combination of the manifestation code preceded by the underlying disease code in the primary field.

Structure of the Case-Mix System

Comment: Several commenters suggested adding a fifth level of severity to the clinical dimension, in view of the large score range in the fourth and highest severity level. In contrast, other commenters suggested that 80 groups was too large a number; they recommended greatly reducing the number of groups. A related question was why some groups with a small incidence of episodes warranted establishment of an HHRG.

Response: At this time, we have not changed the basic structure resulting in 80 groups. Adding a fifth clinical severity level would increase the number of groups to 100. Reducing the number of groups may obfuscate the clinical logic we used to help shape the system. Also, we feel it is prudent at this early stage of the model's application to avoid imposing additional structural streamlining before larger data sets become available allowing exploration of refinements to the model.

Comment: A commenter stated that the case-mix system should have as many episodes at the high end of the scale as the low end.

Response: We disagree. It is more important for the structure of the groups to differentiate episodes with similar severity and costliness. Severity and costliness are not evenly distributed in the population of episodes. The most resource intensive episodes are infrequently encountered.

Comment: A commenter criticized the use of a scoring range from 27 to 160 for the highest level of severity in the clinical dimension, saying it is too broad.

Response: In response to several comments on the adequacy of payment for severe wound cases, we have revised the severity score intervals along with making additions to elements in the clinical dimension. We discuss changes to the case-mix system in section IV.G.1.

Comment: It was suggested that the case-mix assignment be made at the end of the episode, because of difficulties agencies may have in obtaining accurate information about patient status early in the episode.

Response: OASIS data collected as part of the comprehensive assessment must be collected within 5 days of the start of care. After collection, agencies have 7 days to ''lock'' the assessment. Therefore, agencies have a maximum of 12 days to establish the case-mix assignment. We think this time period is adequate to resolve uncertainties about the health and functional status items on the OASIS. Further, the therapy threshold used in the case-mix system is projected at the start of care, and is updated by the end of the episode to determine the final case-mix adjusted payment.

Omission of Time Spent Outside the Home From the Calculation of Resource Costs

Comment: We received comments faulting the case-mix adjuster for limiting the measurement of resource costs to time spent in the home. Commenters argued that time spent

outside of the home, travel time, and resource costs of equipment and supplies should be included. One commenter maintained that failure to account for medical supplies leads to two inconsistent reimbursement methodologies, one for services and the other for supplies. In the case of wound patients using very expensive dressings and supplies, commenters argued the resource cost is seriously underestimated.

Response: We acknowledge the underlying concern from the commenter but we are limited in our ability to address this comment in the near term. Variation in costs other than visit time is a subject for careful empirical study that will take time. Were we to adopt imprecise estimates in a hasty attempt to rectify perceived errors in the payment weights, we would risk introducing other errors and potential inequities into the payment system. The model as developed to date assumes that the omitted resource costs are directly proportional to time spent in the home. In future years, we plan to consider methods for testing this assumption. Studies to directly account for costs beyond time spent in the home pose significant challenges in terms of their feasibility, cost, and reliability. The Abt study did not attempt to measure non-home resource costs because it was believed the complexity of the necessary measurement procedures would jeopardize agency recruitment and data accuracy.

Use of OASIS Data To Validate the Case-Mix System

Comment: Several commenters advised us against using early OASIS data to validate the case-mix grouping system. They believe that the data are flawed because agency personnel are still learning how to conduct assessments. A couple of commenters sought confirmation that we validated the system, and requested information about how we validated the system.

Response: It is not possible to use the OASIS data for complete system validation, because validation requires information about resource cost as well as patient characteristics. OASIS data provide only patient characteristics. However, as discussed in the proposed rule, we did validate the case-mix grouping system using a split sample methodology with the Abt case-mix data (see Abt Associates, Second Interim Report, September 24, 1999).

Our primary purpose for using the OASIS data was for payment allocation during the first year of PPS. Specifically, we hoped the OASIS data could be used to estimate the distribution of case-mix in the population, which is information needed to accurately establish the standardized payment amount. As described elsewhere in this regulation, we used OASIS data to achieve this purpose.

Comment: A few commenters recommended allowing therapy assistant services and rehabilitation nurse services to count towards the therapy threshold.

Response: We do not believe that any changes to the current coverage rules governing the coverage of physical therapy, occupational therapy, and speech-language pathology services under the Medicare home health benefit is warranted at this time. If we believe coverage revisions are necessary for future refinements to the HHA PPS, we may consider revisiting the coverage guidelines at that later time. Under the case mix methodology, patients with intense therapeutic needs are classified in higher payment groups. A physical therapist, occupational therapist or speech-language pathologist would have to diagnose the therapeutic needs of the patient. If significant assistant substitution occurs under PPS, we may focus medical review efforts or reprice the case-mix groups. Rehabilitation nurses have never met the personnel qualifications or coverage criteria for physical therapy, occupational therapy or speech-language pathology services under the Medicare home health benefit.

Other Comments

Comment: A commenter stated that we should add more variables to the case-mix system to increase the R-squared.

Response: In an effort to better capture resource cost for severe wound patients, we have added several more variables as explained in the discussion of changes to the case-mix system in section IV.G. The R-squared has increased. Future refinement activities may result in more additions and better ways to use existing variables.

Comment: A few commenters asserted that an R-squared (proportion of variation explained) of .32 for the case-mix system is too low, and one asked whether the system was validated.

Response: We used a split sample methodology to validate the case-mix system. The R-squared for the validation sample changed little. The R-squared for the initial case-mix system is comparable to that for other case-mix systems in their early stages. We should expect future research, using better data (such as improved diagnosis coding) and more observations, to result in higher predictive power.

Comment: Some commenters recommended that we add to the case-mix model OASIS items measuring such nonclinical factors as safety hazards and other environmental variables, and socioeconomic status variables.

Response: OASIS includes these variables to use as risk factors in analyses of the outcomes of home health care. But as we discussed in the proposed rule, we do not believe they are appropriate factors in determining payment.

Comment: Some commenters disagreed with our decision to exclude items dealing with signs and symptoms such as fluid retention and diet, on the grounds that these are important clinical changes with a direct relationship to care quality and outcomes.

Response: As we noted in the proposed rule, we are concerned about the vulnerability to manipulation for payment maximization of some possibly transient clinical items. Our statistical analysis also suggests weakness in their scientific reliability. Moreover, inclusion of these items would require a change to the OASIS data collection procedure, causing additional burden on home health agencies. Lastly, after all other elements are included in the model, they do not make any independent contribution to explaining variation in resource use.

Comment: A commenter stated that patients with low or moderate scores who need to be observed and assessed, and taught how to manage their medication and diagnosis, would not receive adequate reimbursement. A couple of other commenters suggested adding variables concerning multiple medications.

Response: During the early phases of model development, there were indications that a variable measuring multiple medications would be useful, but as it was not an OASIS variable we sought to substitute similar OASIS items. We found substitutes in the two OASIS variables measuring the patient's ability to manage oral and injectable medications. Statistical results suggest only one of these variables (injectable medications management) contributes independently to explaining resource variation after accounting for the other variables in the case-mix model. However, we believe using this variable makes the case-mix system vulnerable to manipulation, and have decided against including it at this time. As we refine the case-mix system, we will continue to look for ways to capture nursing functions mentioned in the comment.

Comment: Two commenters responded critically to the absence of

respiratory treatments from the clinical dimension.

Response: This variable was excluded from the model because it was statistically insignificant and inversely related to resource cost.

Comment: Several commenters stated that the system should specifically allocate points for limitations affecting medication management, meal preparation, feeding, and the ability to structure time.

Response: Measures of medication administration, meal preparation, and feeding dependence were tested but did not contribute significantly to explaining home health resource use. We note the case-mix system recognizes patients with memory deficit, impaired decision-making and behavior problems.

Comment: Stating that patients with multiple treatments at home (intravenous infusion, parenteral/enteral therapies, OASIS M0250) are often observed in home care, a commenter asked why these patients are not assigned the sum of scores for each treatment.

Response: At this time the case-mix model does not assign the sum of two scores when patients are receiving multiple treatments. In terms of care quality, we are concerned about the potential incentive to make patients' care more complex if scores for this OASIS item are additive. Currently, patients who receive both intravenous infusion and enteral nutrition, the most plausible combination, would receive 24 points for enteral nutrition, the highest score possible among the three treatments and the second-highest single score in the clinical dimension. Given our understanding of the needs these patients may present, this score seems appropriate pending further review of data for multiple-treatment patients. The Abt sample did not contain any patients receiving more than one of these treatments. As these treatments do not appear to produce additive work, we believe it is prudent to wait until more-reliable scores for multiple-treatment patients can be developed during refinement activities using larger data sets.

Comment: Commenters also criticized us for omitting types of specific OASIS items or response categories that indicate lower severity than items/categories currently in the case-mix model. For example, one commenter stated, the presence of ''any pain'' would affect the plan of care. The pain response categories that are allocated points are ''daily but not constantly'' and ''all of the time'.

Response: We understand the commenter's recommendation for more specificity in the case-mix system. We note that generally, the case-mix model captures levels of severity that were reliably associated with variations in resource use. Constructing variables for the model involved both statistically based decisions as well as judgments about how many grades of distinction are desirable from clinical, policy, and structural points of view. For example, in response to comments about wound care patients, we have elaborated certain wound variables to capture finer distinctions in wound status, while retaining statistical reliability for the clinical dimension. We have traded off some structural parsimony for slightly increased accuracy. As larger data sets become available to refine the case-mix system, we may have an opportunity to incorporate still more detailed variable levels, but we will continue to evaluate them in light of their clinical, policy, and structural implications.

Comment: A commenter wondered whether listing M0530 (when does urinary incontinence occur?) rather than M0520 (urinary incontinence or urinary catheter presence) in the clinical dimension was a typographical error.

Response: No, it is not. As we noted in the proposed rule, we avoided M0520 because of concern that using it might promote negative practice patterns. M0530 is a stronger measure of the impact of incontinence on home care because it takes timed voiding into account.

Comment: A couple of commenters stated that the case-mix adjuster should identify patients with urostomy because services and teaching requirements exceed those for bowel ostomy patients.

Response: OASIS does not currently allow identification of urostomy patients. We will consider this suggestion for future OASIS studies.

Comment: A commenter asked why hearing status is not included, while vision status is.

Response: We tested hearing problems as part of a set of neurological, cognitive, sensory, and behavioral impairments during our development of the case-mix system. Few of these variables contributed meaningfully to the case-mix model, and for some types of clinically severe patients these impairments were inversely related to resource cost. We were ultimately able to include both vision problems (M0390) and behavioral problems (M0610) in the clinical dimension as statistically significant variables positively related to resource cost.

Comment: One commenter suggested that we change OASIS item M0390 on vision status to identify patients who have difficulty accommodating to distance.

Response: We will consider testing this change in research on modifications to OASIS.

Comment: A commenter requested clarification of the definition in the vision status item (M0390).

Response: All OASIS items, including this item, are discussed in the OASIS Implementation Manual available on the HCFA Web site.

Comment: A commenter stated that OASIS functional items are not sensitive to patient progression, so that the patient who improves is still rated at the same level after improvement. The commenter cited the case of the patient who is dependent in bathing in bed, and progresses to independent in bathing in bed.

Response: This comment appears to address the use of OASIS items for outcome measurement. During the testing of outcome measures for use in home health care, it was necessary to balance several competing demands. One of these demands was for sufficient ''rigor'' in the outcome measures and data items, including the data item's likelihood of consistent application by the clinicians making the assessment. Another demand was a more practical one—would the home health agency's staff be able to use the item in its day-to-day functioning? Because every OASIS item that now has several levels of a scale could most likely be expanded to many more scale levels, several questions must be asked as part of the evaluation of OASIS items. For example, would the item be perceived as practical for use by clinicians? Would the resulting outcome measures be valuable in evaluating quality of care across agencies? Would the item have a high incidence of consistent application? These are among the evaluation criteria we would apply as the outcome measures and the OASIS items continue to evolve over time.

Comment: A commenter said the system should recognize medically underserved patients.

Response: The OASIS assessment does not clearly identify medically underserved patients. However, a variable relating to Medicaid status is reported on the OASIS assessment and can be considered a proxy indicator. During our system development work on the Abt sample we tested the Medicaid variable (which indicates whether Medicaid was among the patient's payment sources). We found that it did not contribute to explaining variation in resource use.

Comment: A commenter stated that home health aide supervisory visits should be included in the case rates, and the agency should be able to bill for those visits.

Response: Time spent in the home, including time spent on supervisory visits, was recorded in the visit log data submitted to Abt Associates by agencies participating in the case-mix research. This means that the case-mix relative weights should reflect any case-mix group differences in supervisory time. Supervisory visits are also in the cost base for the average cost per-visit computations used in the PPS episode rates. We are making no changes in payment policy regarding billing for supervisory visits.

Comment: A commenter, stating that the case-mix system inadequately accounts for costs of behavioral patients, asked how well such patients were represented in the Abt sample.

Response: We believe these patients were adequately represented. Approximately 4.5 percent of the Abt sample had a primary diagnosis code of a mental disorder. Approximately 2.6 percent received psychiatric nursing services at home. About 14 percent were classifiable as having chronic cognitive, mental, or behavioral problems. Approximately one-quarter of the sample had current problems due to one or more of the behaviors listed in OASIS M0610.

Comment: A commenter suggested that refinement activities include examining outliers to see whether the case-mix categories involved are improperly weighted.

Response: We plan to examine the data as suggested.

Comment: One commenter questioned whether we examined the validity of the relative weights. A related recommendation was to validate the relative weights on a large national data set after the first year of PPS.

Response: We examined various measures of fit of the case-mix model to episode-cost data to judge the model's performance and, by implication, the validity of the relative case-mix weights derived from it. Most of these fit measures are reported and discussed in the Abt Associates Second Interim Report (September 24, 1999). As explained in the proposed rule, we derived the relative weights from a straightforward regression equation that estimates the average addition to resource cost due to each severity level above the lowest-severity case-mix group (C0F0S0). This regression equation, estimated from the Abt sample data, performed well. We used case-mix-group means estimated from the coefficients of the regression equation to compute the relative case-mix weights. We plan to re-examine the accuracy of the relative weights periodically.

Comment: A commenter asked whether the mean or median was used to calculate the relative case-mix weights.

Response: We used the mean estimated from the regression equation described in the previous response.

Comment: A commenter requested that we disclose the computations for independent review.

Response: In the section of the rule regarding the calculation of the case-mix relative weights, we show the regression equation coefficients and the mean resource cost calculated for each case-mix group from the regression coefficients.

Comment: A commenter stated that we should release data showing the incidence of cases in the groups used to define the relative weights.

Response: Appendix C in the Abt Associates Second Interim Report (available on the HCFA website) shows the incidence of cases in each case-mix group in the sample.

Comment: A commenter questioned whether hospital-based agencies were adequately represented in the sample used to develop the case-mix system.

Response: We believe that hospital-based agencies were adequately represented in the sample. About one-third of the 90 agencies participating in the Abt study were hospital-based and one-third of the episodes in the Abt analytic sample came from hospital-based agencies. The hospital-based agencies were distributed across the four census regions, urban and rural locations, and represented varying practice patterns. The total development sample included more than 9,000 episodes (Abt Associates Second Interim Report, September 24, 1999). The sample for deriving case-mix weights in the final rule included more than 26,500 episodes.

Phase II Per-Episode PPS Demonstration

Comment: One commenter asked whether demonstration agencies deliberately avoided higher-acuity patients while participating in the demonstration project.

Response: The demonstration evaluation study examined this question. Analyses suggested that PPS agencies were no less likely than non-PPS agencies to admit a patient with a serious medical condition, limitations in activities of daily living, or other conditions predictive of higher-than-average service needs. Furthermore, the demonstration did not appear to affect the admission of patients expected to have relatively high costs per visit.

Comment: A commenter wanted to know why data on pages 58143 and 58150 in the proposed rule showed different percentages of discharges at 60 days and 120 days. Page 58143 cites completion rates of 60 percent and 73 percent in 60 and 120 days, respectively. Page 58150 cites completion rates of 46 percent and 62 percent, respectively.

Response: Data cited on page 58143 were completion rates for 39 agencies paid prospectively under the Phase II per-episode prospective payment demonstration in the first year of the demonstration (1995-96). Data cited on page 58150 are national averages from an episode file constructed from 1997 paid claims. Research would suggest that the differences stem mainly from the incentives of prospective payment.

L. Episode Rate Methodology

Comment: Several commenters suggested that we include the amounts for new billing and financial systems in the PPS episode rate.

Response: We do not foresee any major changes to the billing and financial systems for home health agencies that would justify an increase in the rate amount. Home health agencies will still use and submit the same claim forms that are currently being used under IPS. With only minimal changes in bill content we will be furnishing free grouping software to all HHAs. If an HHA elects to purchase different or more deluxe software from its vendors, that would be an individual business decision of the HHA. It is primarily the fiscal intermediaries systems that will require changes in order to process home health claims under PPS. We will not reimburse agencies for modifications to their internal billing and financial systems beyond what is already included as overhead costs reported on the cost report.

Comment: Several commenters requested that we not use the most current data for developing the home health PPS episode rates in order to avoid incorporating the effects of IPS.

Response: In developing the final PPS episode payment rate, the primary influence for the final amount is the budget neutrality target. The statute requires that the total amounts payable under HHA PPS be equal to the total amount that would have been made if HHA PPS had not been in effect. This numeric value is based on actuarial estimates of future home health spending and utilization in the aggregate. Since the projected spending

is based on historical trends derived using the most recent data available, IPS cannot be ignored. Using data prior to the implementation of IPS would not reflect current home health utilization and spending.

Comment: One commenter suggested that we revise the computations of the average cost per visit to only apply the cost limit adjustment factor to those disciplines that were over the per-visit cost limits.

Response: The per-visit cost limit has been applied on an aggregate basis, not on a per-discipline basis. Separating the disciplines proved too difficult to achieve and would be of questionable worth. The cost limit adjustment factor was determined by dividing the aggregate cost limit amount by the aggregate reasonable cost amount. If the factor was less that 1.0, then the factor was applied across all disciplines. If we had only applied it to the disciplines that were over the limits, then we would not have recognized the actual impact of the cost limits.

M. Audited Cost Report Sample

Comment: Several commenters questioned the accuracy and use of the statutorily required most current audited cost report data available to the Secretary to calculate the PPS rates. Commenters questioned whether better, more accurate data may exist than the 1997 audited cost report data set forth in the proposed rule.

Response: For the proposed rule, data from audited cost reports received by an HCFA determined deadline date were used for the calculation of the proposed HHA PPS rates. Even though all audited cost reports were not available (for reasons such as, suspensions, investigations, natural disasters, etc.), HCFA had to set a cut-off date to meet the stringent time constraints for completing the proposed rule. Any additional audited cost report data files that were received by HCFA Central Office (CO) beyond the deadline were not included in the rate calculations for the proposed rule. Since then, audited cost reports from the sample may have been appealed, reopened, and revised resulting in an updated version of the cost report data available for calculation of the rates for the final rule. Even after the publication of the proposed rule, we required fiscal intermediaries to resubmit any reopened audited cost reports and have that more recent, accurate data available for final rule calculations through the first week of January, 2000. This process resulted in an additional seven providers for which we now have audited cost reports for FY 1997. Additionally, during the above-described additional time period, we received 23 reopened audited cost reports with newer and more accurate data for use in the final rule calculations.

Comment: Commenters were concerned with pre-IPS cost data being used and that 1997 data may not be an adequate time period to reflect the cost of providing care today.

Response: HCFA is required, in its development of a PPS for home health agencies, to use the most current audited cost report data available. At present, 1997 audited cost reports are the most current audited cost reports available of a representative sample of HHAs. The 1997 audited cost data is updated by the market basket in order to make it more reflective of the cost of providing care today.

Comment: Commenters were concerned that not all types of HHAs, with respect to their being considered large, small, urban, rural, for profit, not-for-profit, for example, were adequately represented in the audited cost report sample used to construct the PPS rates.

Response: The sample was designed to be representative of the home health industry, including census region, urban versus rural location, and large versus small agencies. The sample included each provider type (freestanding not-for-profit, freestanding for-profit, freestanding governmental, and provider-based), which are referred to as strata in sampling terms. The design of the sample then took into account the number of providers and the variation in cost and beneficiaries in each stratum, resulting in a representative sample of the home health industry.

Comment: A few commenters were concerned with the sample design which excluded ''very small'' agencies.

Response: Agencies with fewer than 50 Medicare beneficiaries were excluded from the sample list of agencies for development of the home health PPS. These agencies were judged to be atypical in their costs and utilization. This would particularly be the case if the agency is a large agency that happens to have only a small Medicare business. Prior PPS demonstrations also excluded these low-volume providers from participation for similar reasons.

Comment: Commenters raised concern about rebasing for FY 2002 based on a 100 percent sample of cost reports. Commenters further recommended that if the future PPS data varies from the FY 2001 base year or their proposed revised approach to rebase for FY 2002, that adjustments be made to the standards on which the system is based.

Response: HCFA has no statutory authority to rebase the home health PPS on 100 percent cost report data. We will continue to monitor the effects of the policies governing the PPS system.

N. Cost Outlier Payments

Comment: Commenters generally supported the outlier policy but often disagreed with specific aspects of the proposed policy. Many commenters stated that protection from the financial risk of catastrophic cases was important. These commenters frequently identified severe wound care patients and non-self injecting diabetics as the types of patients that pose the greatest financial risk because of the concern that the HHRG system may not adequately recognize their costs. In addition, commenters tended to support greater financial protection against large losses, favoring a greater concentration of outlier payments on the most expensive cases, which can be accomplished by using a higher fixed dollar loss amount and a higher loss sharing ratio. Several commenters wanted provisions totally incompatible with the statutory constraint that total outlier payments be no greater than 5 percent of total payments including outliers, such as no fixed dollar loss and a higher loss sharing ratio, or even full cost reimbursement of outlier cases. However, several commenters argued that if greater catastrophic protection could not be provided, 5 percent higher episode payments for all episodes would be preferable to the proposed outlier policy.

Response: As stated in the proposed rule, the provision for outlier payments is optional under section 1895(b)(5) of the Act. However, if outlier payments are included in the PPS, the statute requires that total outlier payments be no more than 5 percent of total payments, including outlier payments. Section 1895(b)(3)(C) of the Act also requires that the episode payment amounts be adjusted to effectively pay for outlier payments within the same level of estimated total spending. These statutory requirements place rather strict limits upon the additional payments that can be directed to unusually expensive cases.

Before deciding to exercise our discretionary authority to include a home health PPS outlier policy in this final rule, we carefully considered the arguments presented in the public comments. We have decided that the benefit to the home health community of adopting an outlier policy consistent with the statute outweighs no outlier policy. However, based on the majority of public comments, we have decided to

increase the loss sharing ratio from the 60 percent set forth in the proposed rule to 80 percent, the same ratio that is used in the inpatient hospital PPS.

Accordingly, the fixed dollar loss amount has also been changed. Our preliminary estimates reported in the proposed rule indicated that a loss-sharing ratio of .80 was consistent with a fixed dollar loss amount equal to 1.35 times the standard episode amount. However, estimates based on the most recent data indicate that the fixed dollar loss amount should be changed to 1.13 times the standard episode amount. Among the commenters supporting a higher loss sharing ratio, while no one suggested a loss sharing ratio lower than .75; some stated that the ratio should be the same as in the inpatient hospital PPS (.80), and others stated that the ratio should be .80 or even .90.

Comment: Several commenters argued that the proposed outlier policy was not sufficient to cover the costs of patients with intensive service needs and would result in inadequate home care being provided to patients with the greatest needs. Some commenters cited the effects of the fixed dollar loss and the loss sharing ratio in severely limiting the additional payment that would be made to outlier cases. Another commenter stated that the outlier threshold should be based on medical necessity without any qualifying financial loss being suffered by the provider, and others stated, in effect, that there should be no fixed dollar loss. Yet another commenter questioned the sufficiency of 5 percent for these types of cases.

Response: As noted above, section 1895(b)(5) of the Act limits the total amount of outlier payments that can be targeted to outlier cases to no more than 5 percent of estimated total payments. It is impossible to eliminate the fixed dollar loss and to pay the full estimated cost in excess of the episode payment. To do so would result in outlier payments far in excess of the 5 percent allowed by the statute. It is also inconsistent with a basic premise of the episode based payment, which is based on average episode costs, and anticipates that ''underpayment'' of some episodes will tend to be balanced by ''overpayment'' of other episodes.

Given the constraint on total outlier payments, we were presented with determining how to beneficially distribute the limited amount of additional payments among the expensive cases. If only the very most expensive of the costly cases qualify for outlier payments, a higher proportion of the total costs of those cases can be paid. Alternatively, if a larger number of costly cases qualify for outlier payments, it is necessary to pay a lower proportion of their total costs. If the fixed dollar loss were eliminated, so that all cases whose estimated costs exceeded the episode amount qualified for outlier payments, the amount of the outlier payment per case would of necessity be so small that there would be little or no benefit for the expensive cases.

As discussed in another comment, we have chosen a loss-sharing ratio of .80 for the final rule instead of the .60 set forth in the proposed rule. We believe that a loss-sharing ratio of 1.00 would go too far in concentrating outlier payments on the most expensive cases. It would further limit the number of cases that could receive any outlier payment and would provide no incentive for agencies to attempt to provide care cost-effectively for outlier cases.

Comment: A number of commenters raised concerns regarding the method used to estimate the cost of an episode in determining outlier payments. Several commenters stated that the ''outlier-standardized per-visit rates'' do not reflect the real cost of visits. Another commenter appeared to misunderstand that we would use per-visit costs for each of the six home health disciplines.

Response: In this final rule, we are revising proposed § 484.240 to modify the per-visit rate used to estimate per-visit costs. We will now use the average cost per visit from the PPS audit sample including the average cost for nonroutine medical supplies and the average OASIS adjustment costs. The only standardization applied to these per-visit costs will be the wage index standardization factor. See Table 6 of the proposed rule (64 FR 58169) and Table 6 in section IV.C. of this final rule.

The wage index standardization factor is included in the per-visit cost because the estimated episode cost will be adjusted by the wage index, just as is the episode payment amount. As a result of these changes from the proposed rule, our estimated cost of an episode will be higher, and more episodes will qualify for higher outlier payments than would have occurred under the originally proposed method. This change in cost methodology will require increasing the fixed dollar loss in order to stay within the 5 percent constraint.

The estimated cost of an episode will be calculated by multiplying the per-visit cost of each discipline by the number of visits in the discipline and computing the total cost for all disciplines.

We understand that the estimated cost will not necessarily accurately measure the actual cost of any individual episode or the actual costs of any single agency. Our method of cost estimation will measure differences among episodes in three factors: the total number of visits, the skill mix of those visits, and the wage costs of the geographical area where the care was provided. This methodology will assume an equitable and timely application of outlier payments among HHAs without introducing the complex and idiosyncratic elements of individual agency cost finding using cost report analysis.

Comment: Several commenters suggested that we consider reimbursing reasonable costs for outlier cases. Other commenters stated that the estimated cost does not include the cost of non-routine medical supplies provided during each outlier episode, and that if we estimated costs in the same manner that is used in the inpatient hospital PPS, we could include the costs of non-routine medical supplies.

Response: It is correct that while the total costs of non-routine medical supplies were included in the episode payment amount, the non-routine medical supplies of an individual episode are not accounted for in calculating the payment for an episode or in outlier calculations. In the inpatient hospital PPS, costs of outlier cases are estimated by multiplying total charges for the services provided during the hospital stay by a hospital-specific cost-to-charge ratio that is determined from the Medicare hospital cost report. Applying this method to the home health PPS would provide a means of including the cost of non-routine medical supplies in the estimated cost of an episode. However, there are two major reasons why we believe that using the estimated visit cost method is necessary. First, we do not have charges for non-routine medical supplies or agency cost-to-charge ratios in the Abt case-mix data that we are using to estimate the outlier policy for the first year of the PPS. Therefore, we are unable to use the cost-to-charge ratio method at this time. Second, we would like to avoid making the Medicare cost report a necessary part of determining an agency's payments under the home health PPS. In particular, we would like to make the new system independent of the burdensome and idiosyncratic cost-finding process of the previous, reasonable cost-based payment system.

Comment: Some commenters indicated a misunderstanding about the application of the wage index in calculating outlier payments. The

confusion was whether the fixed dollar loss was adjusted by the wage index.

Response: The fixed dollar loss amount is wage-adjusted in exactly the same manner that the standard episode payment is wage-adjusted. As a result, the fixed dollar loss will be the same proportion of the episode payment in all wage index areas. In nominal dollars, the outlier threshold for an episode in a low wage index area is lower than the outlier threshold for an episode in the same HHRG in a high wage index area. The outlier payment is also wage-adjusted. Hence, the outlier payment for an episode will be the same proportion of the total payment for that episode whether the episode of care is provided in a low or a high wage index area.

Comment: Several commenters asked operational questions about the outlier policy and how outlier payments would actually be made. For example, one commenter asked us to clarify how and when outlier payments would be made. Another asked who initiates an outlier request and whether it would be automated. Others asked how the 5 percent would be determined and how information on outlier payments would be communicated to agencies. Another commenter asked what our policy would be if total outlier payments are significantly different than the 5 percent amount. Another commenter asked how outlier payments would be tracked and capped nationally and how agencies would know when the outlier pool had been exhausted. Finally, there was the question whether the 5 percent applied to individual agencies or all agencies in the aggregate.

Response: Outlier payments will be made automatically by RHHI through the normal claims processing system. When the RHHI determines the final episode payment based on the claim submitted by the agency, as part of determining the appropriate payment for the episode, the RHHI system estimates the imputed cost of the episode under the outlier methodology. If the cost exceeds the outlier threshold for the HHRG to which the episode is assigned, then an outlier payment will automatically be calculated for the episode. The agency will know when it receives an outlier payment for an episode because it will be part of the final payment for the episode and noted on the remittance advice.

It is important to understand that, according to section 1895(b)(5) of the Act, the 5 percent constraint applies to estimated total payments, not actual total payments. Each year, we will establish, the loss-sharing ratio and the fixed dollar loss values that will be used throughout the next fiscal year to calculate outlier payments. There will be no reconciliation of actual outlier payments to the 5 percent target either during a current fiscal year or in any subsequent fiscal years. If actual outlier payments during a given year exceed 5 percent of actual total payments, there will be no attempt to recoup the difference. Similarly, if total outlier payments in a year fall short of 5 percent of actual total payments, there will be no additional payments made to agencies. Such information will, however, be part of the analysis conducted for setting the appropriate threshold in subsequent years.

Finally, there is no direct relationship between the 5 percent limit on total outlier payments and the percent of outlier payments that an individual agency may receive. Depending on the agency's caseload during the year, the percentage of outlier payment to its total payments as outlier payments will likely vary. The 5 percent constraint applies to all agencies in the aggregate and not to individual agencies.

Comment: One commenter questioned why we have no outlier policy for LUPA episodes.

Response: No additional payments will be made for LUPA episodes beyond the LUPA payment. However, it should be noted that in this final rule, we have changed the per-visit costs to be used in computing the LUPA payment so that the same per-visit amounts will be used for the LUPA payment as that used in estimating the cost of a regular 60-day episode.

Comment: A commenter stated that we should implement a payment ceiling for outlier cases (such as 175 percent of the HHRG payment) and use a 15 percent adjustment to fund the outlier pool.

Response: Since a basic objective of outlier payments is to increase payments to the most costly cases, we do not think that outlier payments should be limited to some percent of the HHRG payment. The effect of such a ceiling would be to allow other less costly cases to receive higher relative outlier payments. As to the latter comment, a 15 percent outlier adjustment is not permitted by the statute, which sets 5 percent of total estimated payments as the maximum amount of outlier payments.

Comment: One commenter suggested that we eliminate outliers and recalculate the case-mix to include long stay cases as part of the HHRG system.

Response: ''Long stay'' cases are as much a part of the HHRG system as shorter term cases, and will not necessarily become outlier cases. As the system provides for unlimited 60-day periods, provided that patients continue to be eligible for Medicare home health services for each 60-day period, HHAs will receive additional episode payments based on the assigned HHRG for each episode. Thus, length of stay is not a factor leading to underpayments. The purpose of the outlier policy is to provide additional payments to cases requiring unusually intensive services within a 60-day episode.

Comment: One commenter stated that a transition policy would be a preferable alternative to the proposed outlier policy.

Response: As discussed previously, we have decided against implementing a transition policy. However, we note that a transition policy could serve some of the same purposes as an outlier policy early in system implementation. For example, a transition policy bases a proportion of the episode payment on the estimated cost (using the same method as we apply in the outlier policy) and the rest of the episode payment on the case-mix and wage adjusted episode amount. Such a policy could provide higher total payments to episodes whose estimated cost exceeds the episode payment. However, for all cases whose estimated cost is less than the episode payment, this blended payment would be lower than the episode payment. Because it would potentially change the payment to all episodes, a transition policy has a greater impact on total payments than that of the outlier policy. Whereas the outlier policy is self-financing under the terms of the statute, a broader transition policy would require a different and possibly greater adjustment for budget neutrality. Finally, a transition policy is, as the name indicates, intended to be temporary, and intended to allow providers time to adjust to a new system. In contrast, we intend the outlier policy to be a permanent feature of the payment system.

Comment: One commenter urged us to carefully monitor the impact of the outlier policy and stressed the importance of maintaining an appropriate balance between the total number of outlier patients and the payment per outlier case. Another commenter expressed a preference for refinement of the case-mix system as an alternative to the outlier policy.

Response: We fully agree with the suggestion of both commenters. We will monitor the impact of the outlier policy with the intention of refining it where possible. We will also explore case-mix refinements as we gather the data needed to support the necessary analyses. We are also hopeful that, over time, case-mix refinement may reduce

the need for an outlier policy. We will examine the issue in the future when more information is available.

Comment: Three commenters raised concern about the impact of outliers on specific types of home health agencies. They expressed concern for financial losses that would be incurred by rural agencies, a provider of ''last resort'' whose cases are in need of intensive services, and agencies in States where there are no other publicly funded home and community based services. In addition, a commenter stated that the wage adjusted per-visit costs would be significantly less than the actual per-visit costs in a particular geographical area.

Response: These comments suggest that the outlier policy might be tailored to increase outlier payments for specific agencies on the basis of their location or case-mix. The outlier policy set forth in this rule provides greater compensation for agencies based on the imputed cost of an agency's episodes. There is no data available to us which objectively identifies providers for whom, on some basis, additional payments would be warranted. We believe the PPS system with its various adjustments provides a sound basis for distributing payment in accordance with patient need.

Comment: Some commenters suggested that we apply different outlier criteria to different types of cases. For example, one commenter stated that the outlier payments should be restricted to the 40 non-therapy HHRGs.

Response: We believe that estimated total cost is the best measure we have for identifying outlier cases. The fact that the fixed dollar loss is the same for all cases means that the estimated loss that must be incurred is the same for all cases and thus achieves equity. Even though a therapy case receives a higher episode payment than a non-therapy case, the estimated loss that must be incurred before it qualifies for outlier payments will be the same.

Comment: One commenter recommended a lower fixed dollar loss for wound care cases than for other outlier cases.

Response: We note that a lower fixed dollar loss for wound care cases than for other cases would direct a greater proportion of outlier payments to wound care cases. We have decided against adopting such a policy at this time. As indicated in a previous response, we believe that it is more equitable to let the estimated cost of each episode determine the amount of outlier payments without singling out specific types of cases for special treatment.

Comment: One commenter seemed to argue that a fixed dollar loss equal to or greater than the episode payment amount was impossible empirically and resulted from assumptions we made about episode costs and payments.

Response: This commenter seemed to misunderstand the method we used to estimate the fixed dollar loss amount and the loss-sharing ratio. The estimates of fixed dollar loss amounts and loss-sharing ratios presented in the proposed rule and in this final rule were not based on any assumptions about internal data relationships. As described in the proposed rule, the estimates were derived from modeling simulated payments and estimated costs for the episodes included in the Abt case-mix data set. For this final rule, we conducted the simulations again using an updated Abt data set. We were unable to perform simulations using early OASIS data from the OASIS national repository, because data lags prevented us from linking OASIS data to claims such that they could be included in this final rule. However, we were able to perform a variety of case-mix comparisons between the national OASIS data and the Abt sample data. These comparisons indicated a high degree of conformity between the two data sources. Further, we were able to compare the 1998 episode file developed from Medicare claims and the Abt data to determine how well the distribution of expensive cases matched in the two files. This analysis also supported the use of the Abt data.

O. Budget Neutrality

Comment: A number of commenters raised concerns regarding the budget neutrality target. A few commenters were concerned about the budget target of IPS limits reduced by 15 percent. Another felt expenditures should be based on the Congressional Budget Office projection of expenditures.

Response: Section 302 of BBRA of 1999 amended the statute to delay the 15 percent reduction in spending until one year after the implementation of PPS and further requires the Secretary to report to Congress within 6 months after implementation of PPS on the need for the 15 percent reduction. The statute also requires the budget target to be based on the Secretary's estimate of spending in FY 2001, not the Congressional Budget Office estimate.

Comment: Some commenters asked if we intend to re-evaluate the budget neutrality factor in the future.

Response: Re-evaluating the experience over the next few years and adjusting the rates accordingly could be beneficial. However, the statute does not provide for any adjustment in the budget neutrality factor nor an adjustment to change the program budget target.

Comment: Several commenters were concerned about our projection of the number of episodes in FY 2001. Some mentioned specific reasons for declining episodes such as the changes in venipuncture rules.

Response: Since the time we published the preliminary notice, we have obtained more meaningful data about home health spending and utilization changes. We now have two consecutive year's episode files and have clarified issues related to spending projections such as unsubmitted claims and sequential billing. We are no longer projecting the same number of episodes as we had in CY 1997. Utilization has dropped substantially since that time. However, the reasons for the drop, such as venipuncture changes, cannot be quantified. We have a two-year comparison relating the drop in episodes to the drop in visits within an episode. Based upon the most recent data, we are dropping the projected number of episodes substantially.

Comment: Several commenters took issue with the data to be used as the basis for the rate setting. They felt that we should not use the 1998 data to establish rates as the low utilization associated with IPS would be built into this analysis.

Response: Because the law requires us to establish a PPS that is budget neutral to what would have been paid under IPS, we need the most recent data to help us develop a model of what would have happened under IPS in 2001. Since utilization did drop so dramatically, we feel that it is important to know how the mix of services changed. Use of 1997 data or 1998 data does not necessarily have a direct effect on the level of payment because of the budget neutrality requirement. For example, using 1998 data, with a lower number of visits in an episode than 1997 data, will result in less of an adjustment to obtain budget neutrality to reach projected FY 2001 spending.

Comment: Some commenters suggested that we increase the budget target to reflect the cost of Part B therapies that were provided outside the home health benefit that will now be covered by the PPS rate.

Response: We determined how much of this type of therapy is being provided to current beneficiaries receiving home health services. We added this amount to the target for spending.

Comment: One commenter believed that we should have performed an impact study for rural areas because

such an analysis would have shown the need for separate budget neutrality factors for rural versus urban areas.

Response: We did look at costs per visits in several different types of rural areas versus urban areas. There was no significant difference, therefore we did not create distinct rates for urban versus rural.

Comment: Several commenters argued that we did not provide support for the behavioral adjustment assumed about the percentage of LUPA payments.

Response: Analysis of the 1998 episode file showed that when home health services were broken into 60-day blocks, for 16 percent of the time either a beneficiary had 1 to 4 visits extending outside a continuous period of service or that a beneficiary simply had only 1 to 4 visits within a 60-day period. Of this 16 percent, only 26 percent or 4 percent of the total were cases where only 1 to 4 visits were provided in a single 60-day, non-contiguous period. This four percent would clearly classify as LUPA episodes. It is not clear that those visits simply falling outside the 60 days would, under PPS, qualify as an episode. A plan of care would probably simply include those straggler visits with the preceding episode in many cases. The episode file was created to help us determine the average number of visits and the mix of visits in an episode. The file was not meant to fully reflect a system where payments are made prospectively. The incentives and the management of care under the prospective system we have designed have many differences from a cost-based reimbursement system. Our assumption about the percentage of LUPA episodes is not so much a reflection of a behavioral change but a clarification of how the episode file was constructed. It would not be reasonable to assume that the distribution of visits under PPS will replicate that of IPS. Our assumption that 5 percent of episodes will be LUPA is based on the actuaries' best estimate of what will actually happen under PPS.

Comment: One commenter suggested that we include appropriate assumptions regarding the PEP in the budget neutrality adjustment.

Response: We developed the PEP and the SCIC to benefit both agencies and beneficiaries. The SCIC was created so that beneficiaries whose condition had changed since the start of the episode could continue to be cared for by the same agency. There is a cost to the payment system in allowing this change in condition. Because we do not have adequate data to estimate this cost, our rate setting assumptions could not incorporate the increased cost of changing to a higher case-mix mid-episode. There are some slight savings from using an end date to the PEP which does not equal the start date of the next episode. Again, we did not specifically account for this in determining the budget neutrality factor because as in the case of the SCIC, we do not have concrete data on which to base any cost estimate. We feel that the cost of the SCIC will outweigh any savings from the PEP. This being the case, the rates are not lower than they should be because of assumptions about the PEP.

P. Discharge Issues

Comment: Several commenters raised concern over possible impacts of discharge policies under the new PPS. Commenters requested clarification of our policy governing the situations of patients who are discharged because they are no longer homebound and therefore ineligible for the Medicare home health benefit during the 60-day episode, the patient refuses services or is discharged because of safety, abuse, non-compliance concerns, or dies.

Response: We believe the documented and legitimate event of a patient's death would result in a full episode payment for the HHA. Therefore, if a patient dies on day 35 of an episode, the HHA would receive a full episode payment for that individual. There would be no proportional payment adjustments to the full episode payment. If a patient is discharged because he or she becomes no longer homebound and therefore ineligible for the home health benefit, refuses services, or becomes a documented safety, abuse or non-compliance discharge during the 60-day episode, the HHA would receive a full 60-day episode payment unless the patient became subsequently eligible for the home health benefit during the same 60-day episode and later transferred to another HHA or returned to the same HHA, then the latter situation would result in a PEP adjustment.

Comment: Commenters requested clarification of discharge policies governing an intervening hospital, SNF or hospice admission.

Response: We believe that HHAs should be given the option to discharge the patient within the scope of its own operating policies; however, an HHA discharging a patient as a result of hospital admission during the 60-day episode will not be recognized by Medicare as a discharge for billing and payment purposes. An intervening hospital stay will result in either an applicable SCIC adjustment or, if the Resumption of Care OASIS assessment upon return to home health does not indicate a change in case-mix level, a full 60-day episode payment will be provided spanning the home health episode start of care date prior to the hospital admission, through and including the days of the hospital admission, and ending with the 59th day from the original start of care date.

Comment: Several commenters asked whether a patient could be discharged before the end of the 60-day episode and whether the final bill could be submitted upon discharge before the end of the 60-day episode.

Response: The claim may be submitted upon discharge before the end of the 60-day episode. However, subsequent adjustments to any payment based on the claim may be made due to an intervening event resulting in a PEP adjustment, such as a transfer to another HHA prior to the end of the 60-day episode or discharge and return to the same HHA prior to the end of the 60-day episode.

Comment: A commenter requested clarification of the situation where an HMO fails to notify the HHA of a transfer of coverage, asking whether the HHA would be responsible for that portion of the PPS payment deducted by Medicare.

Response: The common working file data base includes enrollment data that should inform the HHA of the enrollment status of patients under a home health plan of care with their agency. If the beneficiary becomes HMO eligible mid-episode, the 60-day episode payment will be proportionally adjusted with a PEP adjustment. The episode payment will be proportionally adjusted using the span of days based on the billable visit date that the beneficiary was under the care of the HHA prior to the beneficiary transfer to an HMO.

Q. Consolidated Billing

Comment: Several commenters requested clarification of the services governed by the statutorily required consolidated billing requirements under sections 1842(b)(6)(F) and 1862(a) of the Act as amended by section 305 of BBRA. Some commenters were concerned with possible False Claims Act violations.

Response: Section 1842(b)(6)(F) of the Act, enacted by the BBA , and amended by the BBRA, requires the consolidated billing of all covered home health services listed in section 1861(m) of the Act, except for DME covered as a Medicare home health service. Section 305 of BBRA revised the statute to exclude DME covered under the Medicare home health benefit from the consolidated billing requirements. Under PPS, HHAs will be required to bill and receive payment for all covered

home health services listed in section 1861(m) of the Act, except DME during the 60-day episode. Under the current system, issues concerning the False Claims Act are within the purview of the Inspector General who will review any possible claims violation.

Comment: Commenters requested reassurance that parenteral and enteral nutrition was not included in the consolidated billing requirements governing home health PPS.

Response: Perenteral and enteral nutrition services are currently not a covered home health service. Therefore, perenteral and enteral nutrition services are not subject to the consolidated billing requirements and are not included in the PPS episode rate.

Comment: Several commenters requested the elimination of non-routine medical supplies, osteoporosis drugs and the therapies from the consolidated billing requirements governing PPS.

Response: The statute requires all covered home health services listed in section 1861(m) of the Act, except for DME, to be governed by the consolidated billing requirements. HHAs cannot unbundle non-routine medical supplies that are currently covered as a Medicare home health service that may coincidentally have a duplicate Part B payment code for payment. In addition, HHAs cannot unbundle the osteoporosis drug or therapies covered under the Medicare home health benefit. Although the osteoporosis drug covered under the Medicare home health benefit is not included in the PPS rate, it is still governed by the statutorily required consolidated billing requirements.

Comment: Commenters suggested that we remove the requirement for consolidated billing of intern and resident services unless it is a choice of the hospital and the HHAs. Commenters suggested a separate payment amount to those HHAs that will bill for their intern and resident services.

Response: To the extent these services were paid on a reasonable cost basis and covered under the home health benefit, there cannot be separate payment for these services under home health PPS. These services will be subject to the consolidated billing requirements. However, the HHA PPS rates and consolidated billing requirements do not affect Medicare payments to hospitals for graduate medical education or billing requirements.

Comment: Commenters suggested that we establish, at a minimum, a partial episode payment to a nonprimary HHA that can demonstrate they followed the recommended Common Working File (CWF) procedures for CWF verification of home health status before providing care, but received incorrect information about the episode status of the beneficiary.

Response: We believe that HCFA systems will provide the appropriate information in a timely manner so that HHAs may establish primacy for purposes of consolidated billing and corresponding payment. In future refinements to the system we will certainly not rule out the feasibility of this proposal if the data shows that this situation occurs frequently.

Comment: Commenters requested clarification of the procedures HHAs and other providers will follow to communicate the necessary charges of DME and the osteoporosis drug.

Response: The current communication level that is necessary to effectively meet the DME and osteoporosis drug needs of home health patients will continue under PPS. Both DME and the osteoporosis drug are paid outside of the PPS rates. As DME covered as a home health service, is no longer subject to the consolidated billing requirements governing home health PPS, the status quo for the provision of DME will continue under PPS. The osteoporosis drug is subject to the consolidated billing provisions although it is paid outside of the PPS rates. HHAs will no longer be able to unbundle the osteoporosis drug to a Part B supplier. The HHA will have to bill Medicare directly for the osteoporosis drug and any applicable supplier will have to look to the HHA for payment.

Comment: Commenters requested clarification of consolidated billing requirements governing billings and payments for services at hospitals, skilled nursing facilities, and rehabilitation centers when they include equipment too cumbersome to bring to the home.

Response: Payments for services at hospitals, SNFs, and rehabilitation centers when they include equipment too cumbersome to bring to the home have been incorporated into the baseline cost data used to develop the PPS rates and are included in those rates. Those services are also subject to the consolidated billing requirements. Therefore, the HHA cannot unbundle the services to a Part B supplier. The HHA must provide the services either directly or under arrangement and bill Medicare directly for payment.

R. Physician Certification of the HHRG (§ 484.22)

Comment: Several commenters requested the elimination of the proposed requirement governing physician certification of the HHRG. In general, commenters objected to the burden associated with this requirement and questioned its logic. Commenters also argued that physicians would not be able to comply with the requirement of certification of the HHRG.

Response: We proposed to require the physician to certify the appropriate case-mix weight/HHRG as part of the required physician certification of the plan of care. This was an attempt to have the physician more involved in the decentralized delivery of home health services. However, based on the number of negative responses from commenters and our reevaluation of this issue, we have decided to eliminate this requirement and focus our attention on physician certification efforts and education in order to better involve the physician in the delivery of home health services. In this final rule, we are deleting proposed § 424.22(a)(1)(v) to remove this requirement from our regulations.

S. Small Rural Providers

Comment: Several commenters suggested that we recognize several small rural exceptions to the national episode payment rate and LUPA policy that would more appropriately recognize the special needs of small rural providers. Commenters suggested that the payment rates are inadequate to meet the special travel needs and potential economy of scale challenges that commenters believe small rural HHAs encounter. Commenters believed the data used to develop the PPS did not include or adequately reflect the behavior of small rural HHAs, and therefore believed it would be difficult to predict the impact of PPS on small rural HHAs. Conversely, other commenters specifically recommended no exception for small rural HHAs.

Response: In our re-examination of the small rural impact issue, we did not find data to support the rural differentiation suggested in the comments submitted. Our analysis included the subcategorization of data into increasing degrees of rural remoteness. As demonstrated in the analysis below, the subcategories did not yield a significant differentiation in costs associated with resource needs and service delivery in rural areas. We do not believe that rural providers will be disadvantaged under HHA PPS. However, we will continue to look at alternatives regarding beneficiary access to Medicare home health services in remote areas. We will continue to analyze this complex issue with new data under HHA PPS. If and when an adjustment is justified, we will refine the system accordingly.

RURAL CONTINUUM CODE STATUS TABLE

Provider type	Continuum code [1]	Average cost per beneficiary 1997 [2]	Average cost per beneficiary 2001 [3]
Free Standing For Profit Agencies	0	$6,622	$4,079
Free Standing For Profit Agencies	1	12,632	3,939
Free Standing For Profit Agencies	2	7,367	5,397
Free Standing For Profit Agencies	3	7,965	6,577
Free Standing For Profit Agencies	4	6,400	5,330
Free Standing For Profit Agencies	5	7,014	5,997
Free Standing For Profit Agencies	6	6,367	4,230
Free Standing For Profit Agencies	7	7,671	4,333
Free Standing For Profit Agencies	8	5,838	4,971
Free Standing For Profit Agencies	9	4,871	4,266
Free Standing Governmental Agencies	0	3,758	2,589
Free Standing Governmental Agencies	1	2,325	2,370
Free Standing Governmental Agencies	2	4,117	2,938
Free Standing Governmental Agencies	3	4,054	3,407
Free Standing Governmental Agencies	4	3,683	2,975
Free Standing Governmental Agencies	5	4,459	3,495
Free Standing Governmental Agencies	6	3,204	2,375
Free Standing Governmental Agencies	7	3,905	3,253
Free Standing Governmental Agencies	8	3,046	2,572
Free Standing Governmental Agencies	9	3,170	2,477
Free Standing Non-Profit Agencies	0	5,341	3,035
Free Standing Non-Profit Agencies	1	4,258	3,871
Free Standing Non-Profit Agencies	2	4,897	2,991
Free Standing Non-Profit Agencies	3	4,069	3,162
Free Standing Non-Profit Agencies	4	3,279	2,810
Free Standing Non-Profit Agencies	5	6,124	4,630
Free Standing Non-Profit Agencies	6	5,730	3,320
Free Standing Non-Profit Agencies	7	5,146	3,638
Free Standing Non-Profit Agencies	8	3,620	3,692
Free Standing Non-Profit Agencies	9	6,546	4,899
Provider Based Agencies	0	5,488	3,233
Provider Based Agencies	1	4,049	3,498
Provider Based Agencies	2	4,553	3,845
Provider Based Agencies	3	4,418	3,015
Provider Based Agencies	4	2,834	2,757
Provider Based Agencies	5	4,358	3,322
Provider Based Agencies	6	3,973	3,212
Provider Based Agencies	7	4,221	2,938
Provider Based Agencies	8	2,355	1,496
Provider Based Agencies	9	4,553	3,580

[1] Source: Bureau of Census' urban and rural classification of populations.
[2] Source: Audited Cost Report Sample Data.
[3] Source: Audited Cost Report Sample Data updated to FY 2001.

CODE DEFINITIONS*
0 Central counties of metro areas of 1 million population or more
1 Fringe counties of metro areas of 1 million population or more
2 Counties in metro areas of 250,000 to 1 million population
3 Counties in metro areas of fewer than 250,000 population
4 Urban population of 20,000 or more, adjacent to a metro area
5 Urban population of 20,000 or more, not adjacent to a metro area
6 Urban population of 2,500 to 19,999, adjacent to a metro area
7 Urban population of 2,500 to 19,999, not adjacent to a metro area
8 Completely rural or fewer than 2,500 urban population, adjacent to a metro area
9 Completely rural or fewer than 2,500 urban population, not adjacent to a metro area

RURAL FRONTIER STATUS TABLE

Provider type	Frontier status [1]	Average cost per beneficiary 1997 [2]	Average cost per beneficiary 2001 [3]
Free Standing For Profit Agencies	No	$6,858	$4,664
Free Standing For Profit Agencies	Yes	4,179	4,620
Free Standing Governmental Agencies	No	3,579	2,803
Free Standing Governmental Agencies	Yes	2,450	1,758
Free Standing Non-Profit Agencies	No	4,921	3,118
Free Standing Non-Profit Agencies	Yes	6,926	2,785
Provider Based Agencies	No	4,500	3,344
Provider Based Agencies	Yes	3,999	2,942

[1] Frontier Status is defined as 6 or fewer persons per square mile.
Source: ''Definitions of Rural: A Handbook for Health Policy Makers and Researchers (HRSA).''
[2] Source: Audited Cost Report Sample Data.
[3] Source: Audited Cost Report Sample Data updated to FY 2001.

T. Wage Index

Comment: We received several comments regarding the wage index that is used to standardize and adjust the rates. The commenters suggested that the hospital wage index might not adequately represent wages paid by HHAs. Many commenters suggested the development of a home health specific wage index. Several of the commenters that suggested the home health specific wage index believed the hospital wage index did not adequately represent the cost of rural wages. A few commenters expressed concern with our proposed approach that continues to apply the wage index adjustment based on the site of service of beneficiaries rather than the location of the parent office. Several commenters suggested that a few wage index values included in Table 4 of the proposed rule were incorrect. A commenter suggested the application of the latest hospital wage index with exclusion of physician and resident costs and hours from the calculation. Several commenters were concerned with the application of the wage index when the patient transfers mid-episode or relocates during the episode.

Response: As indicated in the proposed rule, we are using the latest pre-floor and pre-reclassified hospital wage index. We used the latest pre-floor and pre-reclassified hospital wage index that was available at the time of publication of the proposed rule.

While we appreciate the intent of a home health specific wage index, we want to point out that our previous efforts in developing such an index resulted in weights that the industry immediately repudiated because it was viewed less favorable than the pre-floor and pre-reclassified hospital wage index. The industry had concerns with the methodology used to develop a home health specific wage index. These concerns coupled with our lack of applicable home health specific data resulted in our adoption of the hospital wage index in our approach to adjusting the labor portion of the formulas. In future refinements to the PPS we will certainly not rule out the feasibility of this recommendation.

We have decided to continue basing the application of the wage index on the site of service of the beneficiary under PPS. We believe this is the most equitable recognition of the wage component for service delivery. Based on commenters concerns with incorrect values included in Table 4 of the proposed rule, we re-examined our data. Based on the data available at the time of publication of the proposed rule, both Tables 4A and B in the proposed rule are correct. We use, and will continue to use the pre-floor and pre-reclassified hospital wage index values which are not published in the annual inpatient hospital PPS notice. We believe this may be the source of some confusion reflected in the comments.

If there is a PEP adjustment, whether it is a transfer or discharge and return to the same HHA during the 60-day episode, the patients site of service is the location of application of the appropriate wage index value. The wage index based on the beneficiary site of service adjusts the labor portion of the original proportional payment and will also adjust the labor portion of the new 60-day episode payment resulting from the intervening event. The PEP adjustment is viewed as two discrete situations: (1) The labor adjustment of the original proportional payment and (2) the labor adjustment of the new 60-day episode payment resulting from the intervening event. If a beneficiary changes locations during the episode (for example, moves in with a family member), then the MSA or non-MSA at the start of the episode governs the labor adjustment of the episode payment for the balance of the episode. The new MSA or non-MSA corresponding to the new location would begin with the subsequent episode.

U. Market Basket

Comment: One commenter requested further clarification of the market basket used to update the cost data for inflation.

Response: We believe the market basket update was adequately described in the proposed rule (64 FR 58149). See section IV.B.2. of this rule for further clarification on the home health market basket. We are available to answer specific questions any commenters may have on an individual basis.

V. Alternative Methods of Care

Comment: Some commenters suggested the need to recognize alternative methods of care under PPS such as telemedicine or other innovations. Commenters recommended such alternative methods as a way to improve service delivery to patients and promote efficiencies.

Response: While we appreciate the intent of this comment, at this point the modality of telemedicine has not been adequately defined nor are there established safety and effectiveness standards across the continuum of products. Thus, we do not intend to change the current definition of a visit governed by § 409.48(c) which states, ''A visit is an episode of personal contact with the beneficiary by staff of the HHA or others under arrangements with the HHA for the purpose of providing a covered service.'' There is nothing to preclude an HHA from adopting telemedicine or other technologies that they believe promote efficiencies, but those untested technologies will not be specifically recognized and reimbursed by Medicare under the home health benefit.

W. Discrimination

Comment: A few commenters argued that the PPS as proposed discriminates

against States, provider types, classes of patients, and the impoverished and poorly educated due to their disproportionate numbers in certain States and regions of the country.

Response: The PPS was developed based on national norms and is intended to eliminate previous patterns of care that never related to patient need. We believe the case-mix methodology, significant change in condition adjustment, and cost outlier payments as developed in the system, treats all patients across the country equitably in relation to their condition.

X. Other Federal Requirements

Comment: A few commenters suggested that HHAs should not be required to comply with new Occupational Safety and Health Administration standards or any other new Federal requirements prior to PPS implementation.

Response: While we appreciate the concerns of the commenters, it is beyond the scope of our authority to place a moratorium on the application of regulations from other Federal agencies or other statutory Medicare requirements.

Y. OASIS Assessment and Plan of Care Certification Transition Concerns

Comment: Several commenters requested clarification of requirements governing OASIS assessments and plan of care certifications for implementation October 1, 2000. Commenters raised concerns regarding burden and costs associated with complying with the requirement that all patients be grouped into appropriate case-mix classifications and plan of care certifications for the October 1, 2000 implementation date.

Response: We addressed this concern in the proposed rule. We proposed to provide a one-time grace period in order to ease the transition to PPS for patients under an established OASIS assessment and certified plan of care prior to PPS implementation on October 1, 2000. We proposed if a beneficiary is under a home health plan of care before October 1, 2000 and the HHA has completed a Start of Care or Follow-Up OASIS assessment earlier than September 1, 2000, the HHA must complete a one-time additional Follow-up OASIS assessment using the modified OASIS B–1(8/2000) at least 5 days before October 1, 2000 for purposes of case-mix classification. The modified OASIS B–1(8/2000) is available on the HCFA Internet site at: http://www.hcfa.gov. If a beneficiary is under an established home health plan of care before October 1, 2000, and the HHA completed a Start of Care or Follow-Up OASIS assessment using the modified OASIS data set B–1(8/2000) on or after September 1, 2000 and does not wish to do a one-time OASIS at the inception of PPS, the HHA may use the earlier OASIS assessment.

We proposed a similar one-month grace period for physician certifications of the plan of care. In the October 28, 1999 proposed rule (64 FR 58195), we proposed, ''If a beneficiary is under an established home health plan of care before October 1, 2000 and the certification date is on or after September 1, 2000 and the HHA in conjunction with a certifying physician does not wish to do a one-time additional recertification of the plan of care at the inception of PPS, the HHA may use the recertification date (September 1, 2000 through September 30, 2000) from the earlier version of the plan of care. This is a one time grace period.'' We believe it is important to allow a one time grace period for plan of care certifications to ease transition concerns.

A beneficiary under an established plan of care as of September 1, 2000, may have a one-time implementation grace period for the plan of care certification requirements for a maximum period of up to 90 days (September 1, 2000 through and including November 29, 2000). This one-time grace period to alleviate implementation burden must be done in conjunction with a certifying physician. The regulatory requirements governing the Medicare home health benefit before implementation of PPS would apply to the certification period up to and including September 30, 2000. Home health agencies in conjunction with a certifying physician will have to document a break in ordered services for the pre-PPS physician ordered services (September 1, 2000 through and including September 30, 2000) and all post-PPS physician ordered services as of PPS implementation on October 1, 2000. The documented break in services during the one-time implementation grace period for the plan of care certification requirements for a maximum period of up to 90 days is required in order to ensure the alignment of all certified episodes and OASIS assessments as of PPS implementation on October 1, 2000.

For example, a Medicare home health eligible patient is under a physician's plan of care and the first billable visit date/start of care date in the plan of care is September 15, 2000. The one-time implementation grace period would reflect a plan of care that specifies physician orders for services furnished both before and after implementation of HHA PPS. The physician orders in the plan of care would reflect services from September 15, 2000 through and including September 30, 2000. All current coverage and payment rules would apply to the services provided on September 15, 2000 through and including September 30, 2000. The plan of care would also specify any services ordered on October 1, 2000 through and including November 29, 2000. The plan of care would reflect the break in services both before and after implementation of HHA PPS. The start of care date/first billable visit date for this patient under PPS in the plan of care is October 1, 2000. The one-time implementation grace period would require the documentation of services in the plan of care that were furnished both before and after implementation of HHA PPS and the documentation of the new PPS start of care date under PPS.

Many commenters raised concern about the potential burden associated with patients who are under a plan of care prior to October 1, 2000, but due to timing, their OASIS schedule did not fall in the post September 1, 2000 grace period time frame. These patients would require OASIS reassessment during the last 5 days of September in order to group the patients for purposes of case-mix classification for the October 1, 2000 PPS effective date. For some HHAs, this could potentially pose a significant implementation burden. Thus, we are revising our proposed approach to permit the completion of the next scheduled OASIS follow-up assessment for those patients under an established home health plan of care prior to September 1, 2000, but on or after August 1, 2000, to be completed at the HHA's discretion during the month of September. Therefore, if the patient is under a home health plan of care that overlaps the month of August 2000, the HHA will have the discretion to complete the next scheduled Follow-Up OASIS Assessment during the month of September. Under the one-time transition grace period, we are not requiring that the OASIS assessment be completed during the required time frame during the last 5 days of the episode certification requirement for August and September 2000. The requirement that the OASIS assessment must be completed during the last 5 days of the certification period in order to case-mix adjust the patient for a subsequent episode certification will resume with PPS implementation effective October 1, 2000. If the patient is under an established certified home health plan of care as of August 1, 2000 through and including August 31, 2000, then the HHA may complete the next

scheduled OASIS follow-up assessment anytime during the month of September 2000. For patients under an established home health plan of care on September 1, 2000 through and including September 30, 2000, then the HHA may use the most recent start of care or follow-up assessment on file for the month of September 2000 to group patients for purposes of case-mix PPS implementation on October 1, 2000.

Z. Billing Issues

Comment: Several commenters requested clarification regarding the billing instructions governing the new PPS.

Response: Due to the highly technical nature of these comments, we will not address those comments in this final rule. However, we will release operational billing instructions to accompany the publication of this final rule.

AA. Cost Reporting Under PPS

Comment: Several commenters recommended that the requirement for an HHA cost report end with PPS implementation.

Response: Cost reporting requirements for HHAs will not end with PPS. As with all other PPS systems there is continued demand for this data. Importantly, the data may be used to monitor, refine, and improve PPS in the future.

Comment: Several commenters requested clarification of the cost reporting requirements governing the October 1, 2000 PPS implementation date. Commenters were concerned with cost reporting periods that do not parallel the implementation date of PPS, October 1, 2000.

Response: All providers will file a full 12-month cost report regardless of their specific cost reporting year. There will be a statistical break in the cost report based on Medicare statistics up through and including September 30, 2000. Under PPS, the cost report will capture all statistical data for both costs and statistics for all subsequent periods. A provider's cost reporting year will not be affected by the implementation of PPS. We will provide more detailed instructions on PPS cost reporting instructions in subsequent program instructions and revisions to the Provider Reimbursement Manual.

Comment: Commenters requested clarification of the application of the interim payment system cost limits for the period of a cost reporting period that may overlap the date of implementation of PPS. Commenters wanted clarification on whether or not the interim payment system cost limits will be prorated.

Response: The interim payment system cost limits (per-visit limit and per-beneficiary limit) will not be prorated. Full application of the limits will apply to the cost reporting year subject to the interim payment system limits.

Comment: A commenter suggested a cost reporting mechanism for the identification of nontraditional home health services and their costs.

Response: Currently, there is no cost reporting mechanism for the separate identification of non-traditional Medicare costs. At their own option, providers may accumulate detailed statistics within their own accounting system.

BB. OASIS Data and Grouper Issues

Many of the OASIS comments were highly technical or not within the parameters of this final rule. Interested parties can get assistance with their queries on an individual basis as well as through the RHHIs and on HCFA's home page. We have provided general responses to the following OASIS data comments:

Comment: A few commenters reported that State OASIS personnel are stating that payments to HHAs under PPS will be based upon actual bills submitted.

Response: This information is incorrect. We have provided State OASIS Educational Coordinators (OEC) with the authority and responsibility to educate HHA providers about the implementation of the clinical aspects of the OASIS data set in their agency, and with the reporting and transmission requirements of the data set needed to go from the agency to the State system. They are not trained to answer questions about reimbursement. The RHHIs have the background and knowledge to educate HHA providers on the reimbursement aspect of HHA PPS. HHAs are free to contact their RHHI on questions concerning reimbursement under HHA PPS.

Comment: One commenter requested that we use the criteria of hospitalization as an indicator for a PEP adjustment due to concerns with the impact on outcome tracking.

Response: As discussed previously in our response to comments concerning the PEP adjustment, we have re-examined our approach due to intervening hospitalizations and potential discharge concerns. We have provided consistency to the extent possible to ensure adequate payment levels and corresponding outcome tracking for quality purposes.

Comment: A few commenters requested clarification of the payment approach for pre- and post-partum Medicare disability patients who are not required to have an OASIS assessment.

Response: While the OASIS data set was not designed for the assessment of the clinical needs of the maternity patient, and the maternity patient is excluded by regulation from the collection of the data set, the reimbursement system will require a home health resource group (HHRG) to be submitted on the claim. In the rare case of a pre-or post-partum Medicare maternity patient, the HHA will need to complete the comprehensive assessments at the specified time points, which are required for production of the HHRG. The HHA can place that HHRG group case-mix number on the claim to receive payment. The HHA is not required to transmit the assessments to the State Agency, but must include those assessments in the clinical record at the agency.

We believe the majority of this type of maternity patient will be held at the LUPA level. If, in the rare instance the patient requires more than four visits, we would suggest the HHA complete an OASIS in order to ensure adequate payment levels. We believe this would be true for the Medicare disabled population under 18. If the patient was at the LUPA level, in all likelihood he or she would be classified into the lowest HHRG level and ultimately paid at the LUPA level at the end of the episode.

Comment: A few commenters requested clarification on the proper OASIS schedule that should be used for a private pay or Medicaid patient who is in a current OASIS assessment period that becomes eligible for Medicare home health benefits during that period.

Response: All Medicare cases require a new Start of Care OASIS assessment to group the patient for payment purposes and assess the patient for care planning at the time the patient becomes Medicare eligible.

Comment: Several commenters requested access to the grouper prior to the publication of the final rule.

Response: We provided draft grouper software on the HHA PPS HCFA website during the comment period of the proposed rule. Providers could download the grouper software in a PC EXCEL format. We plan to also provide the final grouper on the HCFA HHA PPS website.

Comment: Some commenters questioned the affect untimely reporting of OASIS date or the absence of it would have on payment.

Response: An HHRG cannot be generated without a completed OASIS. The RHHI will not accept a billed HHRG unless the OASIS that supports the billed case-mix classification is encoded by the agency, electronically transmitted and accepted by the State's OASIS repository.

Comment: A few commenters were concerned with potential implementation costs associated with the OASIS schedules used to group patients for case-mix purposes.

Response: In section IV.C. of this rule, we set forth the payment methodology for the first year of PPS one-time adjustment reflecting implementation costs associated with revised OASIS schedules needed to classify patients into appropriate categories for payment. We have provided clarification of the proper OASIS assessment schedule used to group patients for case-mix based on the patient's episode status. Further clarification will be provided in subsequent program instructions.

Type of episode or adjustment	OASIS assessment: M0100 & M0825 response selection
1. Initial, whether first or new 60-day episode resulting from PEP Adjustment.	Start of Care: (M0100) RFA 1 and (M0825) select 0—No or 1—Yes*
2. SCIC *with* intervening Hospital Stay during current episode	Resumption of Care: (M0100) RFA 3 and (M0825) is 0—No or 1—Yes* If a patient was transferred to the hospital without agency discharge during the current episode, the required assessment upon return to home is the Resumption of Care assessment (RFA 3). The Resumption of Care assessment is required within 48 hours of the patient's return from the inpatient facility. The Resumption of Care assessment (RFA 3) also serves to determine the appropriate new case-mix assignment for the SCIC adjustment.
3. SCIC *with* intervening Hospital Stay at the end of an episode	Resumption of Care: (M0100) RFA 3 and (M0825) is 0—No or 1—Yes* and Follow up (M0100) RFA4 and (M0825) is 0—No or 1—Yes* If a patient was transferred to the hospital without agency discharge, the required assessment upon return to home is the Resumption of Care assessment (RFA 3). The Resumption of Care assessment is required within 48 hours of the patient's return from the inpatient facility. The recertification (Follow-up, RFA 4) comprehensive assessment is required in the last five days of the certification period; for payment purposes, this assessment is used to determine the case-mix assignment for the subsequent 60-day period. If the second part of the SCIC adjustment occurs in the last five days of the certification period, two comprehensive assessments are required. One assessment will be done for the resumption of care (RFA 3) and (M0825) select 0—No or 1—Yes; the other will be done for the re-certification (Follow-up) assessment (RFA4) and (M0825) select 0—No or 1—Yes.* The reason two assessments are required is that therapy need must be predicted and reported on the OASIS record for each discrete 60 day episode.
4. SCIC *without* intervening Hospital Stay	Other Follow-Up Assessment: (M0100) RFA 5 and (M0825) select 0—No or 1—Yes*
5. Subsequent 60-day episode due to the need for continuous home health care after an initial 60-day episode.	Recertification (Follow-up): (M0100) RFA 4 and (M0825) select 0—No or 1—Yes*

* (M0825) = NA is applicable only when response (M0150)—response 1 (traditional Medicare fee-for-service) is not selected.

CC. Medical Review Under PPS

Comment: A number of commenters expressed concerns pertaining to the initiation of medical review activities for home health claims under the prospective payment system and suggested there should be a moratorium on or a delay of medical review. Others proposed a limit on the amount of and/or the kind of medical review performed.

Response: We believe it is important to implement medical review activities at the start-up of the new prospective payment system. As problems with specific home health claims are identified, contractors will be able to educate the home health agencies to prevent future billing errors. We have been working hard to develop an effective medical review strategy that will guard against program vulnerabilities unique to the PPS environment, be fair to home health providers, and meet the goal of paying claims correctly.

Comment: Commenters asked that we clarify the medical review process. One commenter asked if the RHHIs will change the case-mix assignment based on the medical review determination, and if so, asked what appeals process will be available to the agencies.

Response: For the most part, medical reviewers will continue to perform the same types of reviews that were conducted prior to implementation of PPS. For example, they will review to ensure that the beneficiary meets the requirements for Medicare home health coverage, and that services provided were reasonable and necessary and appropriately documented. One additional aspect of the review strategy will focus on the OASIS information and whether it is supported by documentation in the medical record. If the RHHI determines that a case-mix assignment is not appropriate, they will adjust the case-mix group accordingly. Agencies will continue to have all appeal rights currently associated with home health claims.

Comment: A commenter suggested that we impose time limits on contractors to complete medical review activities within a prescribed amount of time after receiving requested medical documentation.

Response: We have not prescribed specific contractor medical review time frames. We agree that this may be an issue that warrants further consideration; however, it is beyond the scope of this regulation and we will revisit this issue if warranted.

Comment: Several commenters expressed concerns about cash flow

issues if providers are placed on focused medical review and recommended that we prohibit sequential billing. Other commenters asked how medical review of an episode would affect subsequent episodes.

Response: We are sensitive to provider cash flow concerns and desires to balance legitimate provider concerns with Medicare's stewardship responsibilities. Sequential billing is not a requirement in the home health PPS, therefore medical review of one episode will not automatically delay payment for subsequent episodes. However, we may reduce or disapprove requests for anticipated payments in those situations in which protecting Medicare program integrity warrants these actions.

Comment: Several commenters expressed concerns about vulnerabilities presented by the prospective payment system.

Response: We recognize that there are unique program vulnerabilities related to the prospective payment environment. However, we believe we have identified possible vulnerabilities and random review will assist us in assessing vulnerabilities and problems on an ongoing basis. We are working with the RHHIs and home health providers to address them as we develop the medical review strategy.

Comment: A commenter recommended that RHHIs review the patient's plan of care (POC) and all visit documentation before determining whether or not patients qualify for full episode payments or therapy thresholds.

Response: We agree, and for claims selected for medical review, RHHIs will consider all available information from the agency for the episode billed in determining payment. That information may include all visit information such as nursing and therapy notes, treatment and flow charts, and vital sign records, weight charts, and medication records. In addition, the solicited information may also include the OASIS, the patient's POC, physician orders, hospital discharge summaries and transfer forms.

Comment: One commenter asked if HCFA expects significant changes in the numbers of denials under PPS.

Response: It is our goal to reduce payment errors. Because this is a new payment methodology, it is difficult to predict whether there will be changes in the denial rate for home health claims. We believe that education and early intervention is key to ensure proper billing under the new payment methodology, and can help reduce both denials and errors by increasing compliance.

DD. Quality Under PPS

Comment: We received a few comments requesting clarification of the quality improvement approach proposed under PPS.

Response: Efforts are currently underway to develop systems to generate outcome based quality improvement reports based on the OASIS that can be used to assess the quality of care at home health agencies, assist the States in their survey and certification responsibility, and provide information to home health agencies to assist them in ongoing quality improvement. Part of this effort is the implementation of the Home Health Outcome Based Quality Improvement System pilot project where the Peer Review Organizations (PROs) will act in a supportive role to assess and support quality improvement efforts in home health agencies. The Home Health Outcome Based Quality Improvement (HH OBQI) System is being implemented as a pilot project in five States through the PRO program. The HH OBQI system will explore the feasibility of providing assistance to HHAs in their efforts to implement and manage new programs for quality improvement. After a competitive solicitation to all PROs, HCFA selected the Maryland PRO, the Delmarva Foundation for Medical Care, Inc., as the lead or Home Health PRO (HH PRO). As the HH PRO, Delmarva will oversee the implementation of the project, coordinate the efforts of the four pilot PROs, and also serve as the fifth pilot PRO. The PROs for Michigan, New York, Rhode Island, and Virginia have also been selected as pilot PROs. The HH PRO will distribute information and guidance to the pilot PROs based on OASIS outcome reports, and its own analysis of OASIS data obtained from the national OASIS repository. The pilot PROs will, in turn, provide education and consultation to home health agencies to assist them in developing and managing their outcome based quality improvement programs. The pilot PROs will also provide consultation to State agencies, RHHIs and HCFA components in interpreting and using the outcome reports to assess home health quality.

EE. Medicare Secondary Payor (MSP) Under PPS

Comment: A few commenters raised concerns regarding the treatment of MSP under home health PPS.

Response: The statute governing home health PPS was silent regarding the treatment of MSP. The current requirements governing MSP will continue under the home health PPS environment. If warranted, further technical clarification will be provided in operational program instructions.

FF. Appeal Rights Under PPS

Comment: Several commenters requested clarification of provider appeal rights under home health PPS.

Response: Under the home health PPS, HHAs will have appeal rights comparable to the current environment. They will not be able to appeal the request for anticipated payment of the initial percentage payment for the episode, but they will be able to appeal a denial or down-coding by the intermediary where items or services were found as to be noncovered custodial care or were not reasonable and necessary AND where the intermediary finds that the beneficiary or provider should have known that they were excluded from coverage under the program (42 CFR § 405.704(c)).

Comment: Some commenters asked about beneficiary appeal rights under home health PPS, specifically demand billing procedures.

Response: We are currently reviewing demand billing procedures to determine whether they must be modified to take into account differences between HHA reasonable cost billing and the HHA PPS.

GG. Suggestions for HCFA

Comment: Several commenters sent comments on other regulations that were outside the scope of this rule. In addition, some commenters requested changes to the current statutorily required eligibility requirements, plan of care certification requirements, other coverage requirements that were not set forth in the proposed rule and the request to publish aspects of the final regulation on a faster publication track.

Response: These comments cannot be addressed in this rule, as this rule does not pertain to current law governing eligibility or plan of care certification requirements and therefore, we cannot amend these requirements as requested by the commenters. Due to tight timeframes for publication of this rule, we were unable to publish any portion of this rule in a separate rule under a quicker timeframe.

Comment: Several commenters recommended that we review all regulations and manual instructions for consistency.

Response: We have reviewed and will continue to review all current instructions and provide corresponding manual revisions and operational

instructions that reflect the final policies set forth in this rule.

Comment: Several commenters suggested the need for formal quarterly meetings with industry representatives or other industry groups to develop the final rule and provide a forum of open communication.

Response: We will continue to strive to keep the lines of communication open with our external environment. There are several requirements that govern the rulemaking process that inhibit consultation with outside groups. However, we will continue to ensure that we are available to clarify concerns and listen to our stakeholders throughout the process.

IV. Overview of Final Regulation

This final rule sets forth the methodology for the national PPS applicable to all Medicare home health services covered under both Part A and Part B. This final rule incorporates a national 60-day episode payment for all of the reasonable costs of services furnished to an eligible beneficiary under a Medicare home health plan of care. This section describes the components of the national 60-day episode payment and the methodology and data used in computation.

A. Costs and Services Covered by the Payment

The prospective payment applies to all home health services set forth in section 1861(m) of the Act that are covered and paid on a reasonable cost basis under the Medicare home health benefit (except osteoporosis drugs as defined in 1861(kk) which are paid outside PPS) as of the date of the enactment of the BBA, including medical supplies. DME is a covered home health service that is not currently paid on a reasonable cost basis, but is paid on a fee schedule basis when covered as a home health service under the Medicare home health benefit. Under the HHA PPS, DME covered as a home health service as part of the Medicare home health benefit will continue to be paid under the DME fee schedule. A separate payment amount in addition to the prospective payment amount for home health services will be made for DME currently covered as a home health service under the PPS. Although the covered osteoporosis drug under the home health benefit is currently paid on a reasonable cost basis, section 4603(c)(2)(A) of the BBA amended section 1833(a)(2)(A) of the Act to specifically exclude it from the prospective payment rate. In addition, unlike DME which is now excluded from the statutorily required consolidated billing requirement, the osteoporosis drug is included in the consolidated billing requirements.

B. Data Sources Used for the Development of the Payment

1. Audited Cost Report Data

Audit Sample Methodology: As discussed in the response to comments section, we provided an additional time period for intermediaries serving providers in the audited sample to resubmit audited cost reports ending in FY 1997 if the cost reports had been appealed and reopened. This provided us with the opportunity to include revised data in the calculation of the final rates if any of the audited cost reports in the original sample had been appealed, reopened or revised as of January 2000. The result was that we added an additional seven providers from whom we have audited cost report data for FY 1997, resulting in a total of 574 cost reports that have been used in the final rate calculations in this rule. The ''window of opportunity'' resulted in an additional seven audited cost reports. Although the new total number of audited cost reports increased to 574, however, we used only 563 of the 574 providers in the developing of the impacts. From 1997 to 1998, 11 of the 574 providers either closed or merged with another provider. As stated above, we are using CY 1998 utilization data in the PPS rate calculation. There was not 1998 utilization data to match to the audited cost report data for the 11 providers that closed or merged.

- Updating to September 30, 2001. Before computing the average cost per visit for each discipline that would be used to calculate the prospective payment rate, we adjusted the costs from the audit sample by the latest available market basket factors to reflect expected cost increases occurring between the cost reporting periods ending in FY 1997 to September 30, 2001. Multiplying nominal dollars for a given FY end by their respective inflation adjustment factor will express those dollars in the dollar level for the FY ending September 30, 2001. Therefore, we multiplied the total costs for each provider by the appropriate inflation factor shown in the table below. See section IV.B.2. of this regulation for a detailed description of the market basket.
- Nonroutine Medical Supplies Paid on a Reasonable Cost Basis Under a Home Health Plan of Care. Before computing the average cost per episode for non-routine medical supplies paid on a reasonable cost basis under a home health plan of care, we also adjusted the audited cost report data for nonroutine medical supplies using the latest market basket factors to reflect expected cost increases occurring between the cost reporting periods ending in FY 1997 to September 30, 2001.
- Adjusting Costs for Providers Impacted by the Per-Visit Limits. For cost reporting periods ending in FY 1997, Medicare recognized reasonable costs as the lower of the provider's actual costs or the per-visit limit applied in the aggregate for the six disciplines. Because some providers' costs were higher than the per-visit limits applied in the aggregate for the six disciplines, it was necessary to adjust their costs in order to reflect only those costs on which the provider's payment was based. The adjustment factor was calculated by dividing a provider's total visit limit by the total Medicare costs, but only if the total visit limit was less than the total Medicare costs. For those providers who were not impacted by the visit limit, (that is, those subject to their actual reasonable costs) no adjustment was necessary and the adjustment factor was set equal to one. The adjustment factor was applied to each provider's total costs for each discipline. Summing each provider's updated, weighted, and adjusted total costs by the sum of visits for each discipline results in the non-standardized, updated, weighted, and visit limit adjusted average cost per visit by discipline.

2. Home Health Agency Market Basket Index

The data used to develop the HHA PPS payments were adjusted using the latest available market basket factors to reflect expected cost increases occurring between cost reporting periods contained in our database and September 30, 2001. The following inflation factors were used in calculating the HHA PPS:

FACTORS FOR INFLATING DATABASE DOLLARS TO SEPTEMBER 30, 2001

FY end	1996	1997
October 31	1.15736	.....
November 30	1.15468	.....
December 31	1.15203	.....
January 31	.....	1.14946
February 28	.....	1.14697
March 31	.....	1.14451
April 30	.....	1.14203
May 31	.....	1.13952
June 30	.....	1.13693
July 31	.....	1.13420
August 31	.....	1.13132
September 30	.....	1.12841

For each of fiscal years 2002 and 2003, section 1895(b)(3)(B)(ii) of the Act

requires the standard prospective payment amounts to be increased by a factor equal to the home health market basket minus 1.1 percentage points. In addition, for any subsequent fiscal years, the statute requires that the rates be increased by the applicable home health market basket index change.

3. Claims Data

We also conducted analysis on an episode database created from the 1997 and 1998 National Claims History Files using 60-day episodes to define episode lengths. These data were based on use of home health services under the current system. We built a CY 1998 episode data base parallel to the construction of the CY 1997 episode data base set forth in the proposed rule at 64 FR 58149.

Table 1 illustrates the comparison of the distribution of consecutive 60-day episodes that occurred in calendar years 1997 and 1998.

Total number of consecutive 60-day episodes	Distribution based on only 60-day episodes that occurred in the CY 1997 period (percent)	Distribution based on only 60-day episodes that occurred in the CY 1998 period (percent)
1	51	59.5
2	18	19.3
3	8	7.7
4	5	4.1
5	4	2.5
6	3	1.7
7	10	5.2

Table 2 is a comparison of the average number of visits per episode for each discipline for CY 1997 and CY 1998 and Episodes in CY 1997 and CY 1998 with five or more visits.

Average number of visits by discipline	Average based on only 60-day episodes that fell into the CY 1997 period	Average based on only 60-day episodes that fell into the CY 1997 period with visit >4	Average based on only 60-day episodes that fell into the CY 1998 period	Average based on only 60-day episodes that fell into the CY 1998 period with visit >4
Skilled Nursing Services	12.55	14.69	12.1	14.08
Physical Therapy Services	2.35	2.74	2.59	3.05
Occupational Therapy Services	0.41	0.48	0.45	0.53
Speech Pathology Services	0.15	0.18	0.15	0.18
Medical Social Services	0.31	0.36	0.28	0.32
Home Health Aide Services	14.59	17.59	11.28	13.4
Total for all Disciplines	30.36	36.04	26.85	31.56

Table 3 provides analysis of the distribution of disciplines across a series of 60-day episodes in CY 1998.

Total number of 60-day episodes	Episode number within series of 60-day episodes	Percent of skilled nursing services	Percent of home health aide services	Percent of occupational therapy services	Percent of speech pathology services	Percent of medical social services	Percent of physical therapy services
1	1	50	24	3	1	2	20
2	1	46	34	3	1	1	15
2	2	46	37	2	1	1	13
3	1	46	38	2	1	1	11
3	2	45	41	2	1	1	10
3	3	46	42	2	1	1	9
4	1	45	43	2	1	1	8
4	2	45	46	1	1	1	7
4	3	45	46	1	0	1	7
4	4	46	45	1	0	1	6
5	1	45	46	1	0	1	6
5	2	44	48	1	0	1	5
5	3	44	49	1	0	1	5
5	4	44	49	1	0	1	5
5	5	45	47	1	0	1	5
6	1	44	48	1	0	1	6

Total number of 60-day episodes	Episode number within series of 60-day episodes	Percent of skilled nursing services	Percent of home health aide services	Percent of occupational therapy services	Percent of speech pathology services	Percent of medical social services	Percent of physical therapy services
6	2	43	50	1	0	1	5
6	3	43	51	1	0	1	4
6	4	43	51	1	0	1	4
6	5	44	50	1	0	1	4
6	6	45	49	1	0	1	4
7	1	40	56	1	0	1	3
7	2	41	55	0	0	1	3
7	3	41	56	0	0	1	3
7	4	41	56	0	0	1	2
7	5	41	55	0	0	1	2
7	6	42	55	0	0	1	2
7	7	42	55	0	0	0	2
8	1	42	53	1	0	1	4
8	2	42	54	1	0	1	3
8	3	42	53	0	0	1	3
8	4	43	54	0	0	1	3
8	5	43	54	0	0	0	3
8	6	43	53	0	0	0	3
8	7	44	53	0	0	0	3
8	8	44	52	0	0	0	3

National Part B Claims History File—Medical Supplies. Nonroutine medical supplies are also a covered home health service listed in section 1861(m)(5) of the Act. The law governing PPS requires medical supplies to be included in the prospective payment rate and to be subject to the consolidated billing requirements. As discussed in the proposed rule, before PPS implementation, HHAs were not required to bundle all home health services. Specifically, nonroutine medical supplies that have a duplicate Part B code could have been furnished by a supplier rather than the HHA and paid under Part B prior to PPS. Under the current IPS, some HHAs may have chosen to unbundle those non-routine medical supplies that had a corresponding Part B payment. In order to determine the scope of the non-routine medical supplies that could have been unbundled under the current system, we identified 199 HCPCs codes representing those items that would fall into the possible ''unbundled nonroutine medical supply'' category.

As discussed in the response to comment section of this rule, based on several comments we re-examined our approach to the original list of 199 codes. Our analysis yielded a payment approach to non-routine medical supplies included in the PPS rates that uses 178 Part B codes that could have possibly been unbundled to Part B before PPS. We performed the same data analysis on the CY 1998 claims data and the revised list of 178 Part B codes to develop the appropriate payment adjustment amount for non-routine medical supplies that could possibly be unbundled to Part B before PPS that is added to the non-standardized episode payment.

We pulled all claims with the corresponding HCPCs codes from the Part B national claims history file. In order to determine whether the HCPCs codes were related to the beneficiary receiving home health services under a home health plan of care, we linked every Part B claim with one or more of the 199 HCPCs codes to home health episodes from our episode database for both CY 1997 and CY 1998 by beneficiary and dates of service. If a beneficiary received home health services during a 60-day episode and there was a corresponding Part B claim with one of the 178 HCPCs codes that was billed during the same 60-day episode, we identified the item as related to the home health stay. We proposed an additional payment amount of $6.08 to the 60-day episode base rate for those nonroutine medical supplies with corresponding Part B codes that may have been unbundled under the interim payment system.

National Part B Claims History File—Therapies. As discussed above in section III. of this final rule. *Analysis and Responses to Public Comments,* we conducted a parallel analysis of Part B therapy claims that could possibly be related to a home health stay during CY 1997 and CY 1998. Prior to consolidated billing requirements governing PPS, HHAs may have unbundled therapy services to Part B. We believe that this was a rare occurrence. Under PPS, HHAs will be responsible for providing physical therapy, speech language pathology services and occupational therapy either directly or under arrangement. Under subsequent analysis, based upon comments received, we believe that there is a need to recognize these therapy services that could have been unbundled to Part B before PPS in the PPS rates. We conducted claims analysis similar to our approach to identify those non-routine medical supplies that could have been unbundled to Part B. We identified the three therapy services in both Part B outpatient and Part B physician/supplier claims data.

HCFA identified 54 HCPCs codes that represent those services that could fall into the possible ''unbundled therapy related services'' category under Part B Physician/Supplier claims for patients under a home health plan of care before implementation of PPS. We also identified under Part B, therapy services that could have been unbundled and provided in an hospital outpatient setting to patients under a home health plan of care before implementation of PPS. We identified the 17 revenue center code ranges for physical, occupational, and speech therapy services that could have been billed under Part B in a hospital outpatient setting for patients under a home health plan of care before implementation of PPS. HCFA pulled all claims from the Part B Physician/Supplier claims with the corresponding 54 codes above and all claims from the Part B hospital outpatient claims with the corresponding 17 revenue center code ranges. As with our analysis of nonroutine medical supplies that could have been unbundled to Part B before implementation of PPS, HCFA matched